UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

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SEKISUI AMERICA CORPORATION
etT al,

Plaintiffs,

v. 12 CV 3479 (SAS)

RICHARD HART, et al,

Defendants.

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New York, N.Y.
January 17, 2014
10:00 a.m.

Before:

HON. SHIRA A. SCHEINDLIN,

District Judge

APPEARANCES

MORRISON & FOERSTER LLP
Attorneys for Plaintiffs
KAREN HAGBERG, ESQ.
CRAIG B. WHITNEY, ESQ.
LEDA A. MOLOFF, ESQ.
NATALIE ANNE FLEMING NOLEN, EQ.

SULLIVAN & WORCESTER LLP
Attorneys for Defendants
FRANKLIN B. VELIE, ESQ.
JONATHAN G. KORTMANSKY, ESQ.
SIOBHAN BRILEY, ESQ.

(Trial resumed)

(In open court)

CARRIE KUEHN,

called as a witness by the Plaintiff,

having been previously duly sworn, testified as follows:

CROSS-EXAMINATION

BY MR. VELIE: (Continued)

Q. Good morning, Ms. Kuehn.

A. Good morning.

Q. Your report at page 16 -- I'll show it to you if you don't recall it, but you testified yesterday that ADI's definition of design inputs was fundamentally inaccurate. Do you recall that?

A. Yes, I recall that.

MR. VELIE: May I please have Plaintiff's Exhibit 67?

THE COURT: By the way, you did not discuss the case at all with counsel?

THE WITNESS: I did not, your Honor.

Q. Did you discuss the case with anyone?

A. No, I did not.

Q. It's Plaintiff's Exhibit 67 and we're going to be looking together at the page --

THE COURT: Plaintiff's Exhibit 67?

MS. BRILEY: Yes. Do you have it?

THE COURT: If it's in the book.

MR. VELIE: Yes, it should be.

THE COURT: I have it.

Q. Do you have it before you, Ms. Kuehn?

A. Yes.

Q. Please turn to the page which ends 830.

A. I see it.

Q. Do you see where it says 4.6?

A. Yes, I do.

Q. The definition is, "Design input means the physical requirements." Is that what you referred to?

A. I see that, yes.

MR. VELIE: May I please have Defendant's Exhibit 9F's? Do we have to put this on the screen or do we have paper copies?

MS. BRILEY: We have paper copies.

THE COURT: 9F is the section of the CFR. Obviously there's no possible objection to the regulation.

MS. HAGBERG: No, your Honor.

THE COURT: Okay.

Q. And you recognize this, Ms. Kuehn, do you not, as 21 CFR 820.3 --

THE COURT: Point what?

A. I have point 1.

THE COURT: I see on the back is point 3. Point 3, definition.

A. Yes.
Q. And definitions drop down to F?
A. Yes.
Q. Do you see where it says, "Design input means the physical and performance requirements of the device that are used as the basis for device designs"?
A. Yes, I see that.
Q. Do you see, Ms. Kuehn, that is substantially identical to the definition you criticized in the defendant's documents? Yes or no?
A. Yes. No, I see that, but their definition goes on beyond what is written next to design input. My criticism was about the entire characterization of design inputs which is fundamentally incorrect.
Q. You acknowledge with me, do you not, that the definition was correct?
A. Some of the wording in their definition is clearly taken from the CFR's, yes.
Q. Substantially identical?
THE COURT: I don't understand your answer then. You say what you were criticizing was not 4.6 but the subsets 4.6.1 through .9? Is that what you're criticizing?
THE WITNESS: Yes, your Honor. It shows a lack of understanding of what design inputs actually are.
THE COURT: In what way?

THE WITNESS: For example, validation protocols have nothing to do with design inputs. Those come much later in the design process. Product -- let me just look here. The language regarding the 510(k) submissions to earmark the project plan, these are not design inputs, your Honor. These are aspects of other parts of the design process, so when I look -- and this is not the only definition that is incorrect in this SOP. Taken in a whole it shows a lack of understanding of the design control process.

THE COURT: Okay. It does say, "Design input includes, but is not limited to," it lists nine specifics. You're saying none of them are included?

THE WITNESS: Some of them can be used as design inputs, but, for example, as I mentioned, the design validation protocols, the peer process protocols, those are not validations, nor do they have anything to do with design inputs and this type of lack of understanding persists throughout the SOPs. This is simply one example, your Honor.

Q. You say the definition was an example?

A. Yes.

Q. Perhaps we can agree on this. Research use only products, it's okay for a company like ADI to sell research use products to people who are going to use them for research uses only, isn't that correct?

A. If they are correctly labeled per the regulations, then

yes.
Q. So they have to be correctly labeled by the regulation as RUO, research use only?
A. Yes, that's correct.
Q. Otherwise they're not covered by the QSRs, are they?
A. If they are intended for research use only they are not covered by the QSRs.
Q. Ms. Kuehn, you've had a chance to reflect about our discussion yesterday. Are you prepared to acknowledge that you did not get a complete data set or would you like me to take you through more data that you were not given?
A. It would appear that I was missing some information in the data set I reviewed.
Q. Do you have any idea how much data you were missing?
A. I have no idea.
Q. Does the fact that you have no idea how much data you were missing lead you as a scientist, as an expert who is here to help this Court and as an honest person, can you now concede that you have less certainty now than when you gave this report and gave this opinion?
A. Yes.
Q. You are less certain?
A. Yes, I am.
MR. VELIE: This shortens my cross substantially, your Honor. May I have a second?

(Pause)

Q. You gave some testimony yesterday about management review minutes and you thought that the minutes were inadequate, is that correct?

A. That's correct. Well, I'm sorry, let me amend that. Not that the minutes were necessarily inadequate, that the minutes reflected the content of management review meetings that did not meet the requirements.

Q. I so recall. I apologize for mischaracterizing.

A. Okay.

Q. The FDA is not even permitted to look at management review minutes, are they?

A. No, they're not, the idea being that they want to encourage medical device manufacturers to honestly evaluate their own quality systems, and so FDA is not entitled to see management review minutes during inspections.

Q. Let's talk for a minute about the audits.

THE COURT: When you refer to the word audits you mean audits and inspections?

MR. VELIE: Yes, your Honor. I apologize. I, for my sins, I am not an FDA expert.

THE COURT: But I've learned that much. They do inspections.

MR. VELIE: Right.

Q. I want to talk about the Intertek ISO audits and the FDA

inspections. Just in bulk you testified just at the very end of your direct that you thought the audit findings confirm your conclusions, is that correct?

A. I found that the Intertek auditor observed findings and recorded them in his audit reports that were consistent with what I observed in the documents that I reviewed.

Q. We can agree that no Intertek audit team during the relevant period ever withheld ISO certification, isn't that correct?

A. I agree.

Q. Therefore, wouldn't you agree that those trained professional auditors, each audit team saw what you saw and decided it was not sufficiently material to withdraw ISO certification. Can you agree with that?

A. To the extent that they were evaluating ADI for its conformity with the ISO standard, they felt that what they saw was adequate to achieve certification.

Q. The question I asked you is they must have seen these same things that you referred to but just didn't think that they were sufficiently material to withhold ISO certification.

A. I don't know what they were thinking, but they seemed to think that ISO certification was appropriate. That's as far as I can go with that.

Q. Okay. And with respect to the FDA inspections which occurred in 2004 and 2005 before the relevant period and in

2011 after the relevant period, in all instances an EIR was delivered indicating that the FDA was not going to pursue any, they weren't going to send a warning letter and they weren't otherwise going to take any regulatory action, isn't that correct?

A. They closed the inspections in response to whatever they received from ADI following the 483s, that's correct.

Q. So similarly, whatever, before and after the audit period, the FDA saw, and you referred to as supporting your opinion, was insufficiently material to the FDA to require even a warning letter, isn't that correct?

A. A warning letter is a very significant action by FDA. So they are not going to send one just because.

THE COURT: Well, that's what he asked you. It wasn't material enough to send a warning letter.

A. Well, it means they felt the response they already received was adequate. I can't say whether FDA would have considered it material or not. I simply don't know.

THE COURT: Okay, but they didn't consider it material enough to warrant a warning letter?

THE WITNESS: Yes, I would agree. I guess that's true. Yes.

Q. There is, let's look together at one additional audit, Defendant's Exhibit U, which is an audit, what I've been referring to perhaps ignorantly as a customer audit. Do you

prefer supplier audit?
A. It depend on whose perspective you're looking from. So from ADI's perspective it would perhaps be a customer audit. From the auditor's perspective we would refer to this as a supplier audit. Either way I think is fine.
Q. You've seen this before, right? When I say this, I mean DXU.
A. I have not seen this before.
Q. I'm only going to call your attention to two things. One is the date which is 13-14 August 2012, approximately three years plus after Sekisui bought ADI.
A. Okay. I see that.
Q. And I'm going to read from the audit overview and recommendations in the middle of the paragraph where we have marked it in yellow. "The overall risk of the supplier --"
MS. HAGBERG: Your Honor, I have an objection before you ask your question. This is outside the relevant period by three years, your Honor.
MR. VELIE: So conceded.
MS. HAGBERG: And Ms. Kuehn has not looked at anything, at audits that were after 2009 with respect to --
THE COURT: I thought -- maybe I'm confused. The second FDA inspection, wasn't that 2011?
MS. HAGBERG: She did look at that because it related back to the 2004 --

THE COURT: If she can look at that, she can look at this. We can't cherry pick. If she looked at the FDA inspection from 2011 she can now look at the 2012 audit.

Q. I'm calling your attention to the statement in the audit overview and recommendations. I believe it's the third sentence. The overall risk of the supplier is medium with 85 percent of compliance rating?

A. I'm sorry, where are you reading? I was looking at the highlighted version.

Q. It's highlighted on the screen.

A. I see it now.

Q. "The overall risk of the supplier," meaning Sekisui in this case, "is medium with 85 percent of compliance rating. The manufacturing of the product is not a risk, but the QMS," quality management system, "is a risk. SD," Sekisui Diagnostics, three years after the audit is done -- I'm sorry, after the deal is done and they buy ADI, "SD is currently non-compliant to ISO 13485 and FDA standards as per Siemans audit team based on this audit." Do you see that?

A. I do see that.

Q. You do understand, do you not, Ms. Kuehn, that this is the only audit that we have that shows the company non-compliant and it's three years after Sekisui buys it.

A. I see that it says that there. I haven't looked at this audit to see what the scope of it was but it would certainly

indicate that based on the summary.
Q. And just in terms of fixing the date, it's not only three years plus after Sekisui bought but it's only about nine months before you first wrote your report, isn't that right?
A. Approximately a year.
Q. About a year. So a year after they were found for the very first time to be non-compliant you wrote your report saying I find them non-compliant, is that correct?
A. My report focused on the period, the relevant time period in this matter, so I wasn't looking at the current state of Sekisui Diagnostics.
Q. I realize that, but you didn't have all the documents, you had what you were given and we don't know what happened, none of us knows what happened to those documents. But when you finally do your work this company is not in compliance.
A. Based on a supplier/customer audit and their interpretation of the findings they found them to be non-compliant.
MR. VELIE: Your Honor, I have no further cross-examination of this witness.
THE COURT: All right. Any redirect?
MS. HAGBERG: Yes, your Honor.
REDIRECT EXAMINATION
BY MS. HAGBERG:
Q. Let's just stay with this document a moment, DX U. Have you seen this document before?

A. No, I have not.
Q. Would problems that you identified in the 2006-2009 audit continue to exist as of 2012?
THE COURT: I'm sorry, what 2006 to 2009 --
MS. HAGBERG: I'm sorry.
Q. The 2006 to 2009 review that you did, the problems that you identified in your report that existed in 2006 to 2009, would those continue to exist in 2012, some of those?
A. Unless they had been fully remediated, it's possible.
Q. And Mr. Velie also showed you PTX 067. Do you have that in front of you, Ms. Kuehn?
A. Yes, I do.
Q. And he asked you if a product was research use only was it required to comply with good manufacturing practices and 21 CFR 820, is that correct?
A. That's correct.
Q. Is it good practice if you are introducing a product to the market that might become a 510(k) submission to maintain the types of records that are required by the regulations?
A. If the ultimate intent is to commercialize the IVD for clinical diagnostic use then it must go through the design control process if it is considered a class 2 medical device. So even if it starts in the research lab, if it is determined at some point that it could be used in the clinic and going to be marketed commercially for that purpose it needs to go

through the design control process and those documents should be kept, yes.

Q. And if you hadn't done that from the beginning of an RUO product would it be possible to go back and recreate that record?

A. If an RUO product that was intended to only be used for research becomes a product that would be, would like to be used clinically, then, yes, a retrospective design history file should be generated and from the point at which that decision is made a proactive maintenance of design history records should be kept per the regulations.

Q. Thank you.

You were also asked whether FDA is permitted to look at management review minutes. Do you remember that?

A. Yes, I remember that.

Q. And does the fact that the FDA doesn't have access to those mean that a company doesn't have to comply with regulations relating to management review minutes?

A. No, it does not.

Q. In fact, in many of the deficiencies that you identify in the report, if you pass an FDA inspection or you pass an Intertek audit is there still an obligation on a company to comply with the regulations that apply to medical device products?

A. Yes. Just to clarify, you don't really pass an FDA

inspection.
Q. Sorry.
A. That's okay. But, yes, FDA makes it explicitly clear that medical device manufacturers are responsible for compliance to all applicable regulations.
Q. So the fact that you have an inspection and the FDA doesn't notice anything doesn't mean that you are fulfilling all of the obligations of 21 CFR 820, is that correct?
A. That's correct. FDA inspections are designed to target specific subsystems of the quality system regulations and thus a company's quality management system. The idea being that if deficiencies are found in those systems they are indicative of potential deficiencies throughout the quality management system because the system is so integrated within itself, so that's correct, just because FDA doesn't look at something does not mean that the company is in compliance.
Q. And do you have PTX 197 in your binder in front of you?
A. Yes, I do.
Q. Does the FDA tell companies that have been subject to a warning letter just what you said? Could I direct your attention to SEK 524?
THE COURT: Wait a minute, to what? Is there an exhibit number first?
MS. HAGBERG: PTX 197.
THE COURT: Yes, PTX 197, and then?

MS. HAGBERG: Page 93524.

THE COURT: Okay.

MS. HAGBERG: And I'm referring to the next to the last paragraph, the last full paragraph on this page.

Q. Is this part of the language that FDA includes in warning letters?

A. Yes, it is.

Q. And could you read the first two sentences of this?

A. It states, "this letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each applicable requirement of the Act and FDA regulations."

Did you want me to continue?

Q. Why don't you continue. I think it's all relevant to what you said.

A. "The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your quality system."

Q. So the obligation remains on the company to be compliant. It's not whether you get caught. Is that how the regulations

work?
A. That is exactly how the regulations are meant to work.
Q. What about ISO audits? Does ISO look at every aspect of a company's business when it does an audit?
A. ISO again follows an audit procedure that is intended to address conformity with the ISO standard. They are not looking for compliance with the quality system regulations so how they conduct their audit is not necessarily relevant to compliance with the quality system regulation.
Q. Mr. Velie also asked you about the fact that FDA did not return to ADI after the 2005 closing of the prior inspection. Is that significant to you?
A. Not particularly. They could have come back or they could have not. I don't know why they did not come back.
Q. Does FDA make a decision between large companies and small companies and have a resources issue that has to decide where to focus its attention?
THE COURT: I don't think she's familiar with internal FDA decision making. I said yesterday I wouldn't allow her to comment on why the FDA does what it does or doesn't do.
Q. Can you look at DX 5, Ms. Kuehn?
A. I'm sorry, what was that?
Q. Defendant's Exhibit V. Sorry. I read that as a 5.
THE COURT: DX V?
MS. HAGBERG: Yes. I think it was one of the

documents that Mr. Velie asked about yesterday.

THE COURT: That means it's going to take a while for me to go through the pile of exhibits. I have it here, I've got it. That's the response letter of Sekisui on July 7, 2011.

MS. HAGBERG: Yes, your Honor.

THE COURT: Went over the response in some detail.

THE WITNESS: I recall the exhibit. I don't have it immediately in front of me but I recall the exhibit. I can see it on the screen here.

MS. HAGBERG: Okay.

Q. Were you present for the testimony from Mr. Kevin Morrissey?

A. Yes, I was.

Q. Do you recall Mr. Morrissey testifying that ADI wrote this response because they wanted them to understand that ADI did have some overarching documents and that ADI had significant deficiencies in CAPA?

A. I recall something along those lines, yes.

Q. And could you please turn to the second page of this document, SEK 899.

THE COURT: I'm sorry, I don't really understand your question because it was completely leading, then she said "I recall something along those lines." That makes your question testimony and I don't understand it. What it says -- I'm reading back your question. "Do you recall Mr. Morrissey

testifying that ADI wrote this response because they wanted them" -- I'll stop there. ADI wanted FDA?

MS. HAGBERG: Yes.

THE COURT: ADI wanted FDA to understand that ADI did have some overarching documents? What are overarching documents?

MS. HAGBERG: Documents that might deal on a very high level, we looked at GEN 41.

THE COURT: Overarching documents and that ADI had significant deficiencies in CAPA?

MS. HAGBERG: That was Mr. Morrissey's testimony.

THE COURT: That ADI wanted FDA to know that ADI had significant deficiencies in CAPA?

MS. HAGBERG: That's correct, your Honor. That's my question.

THE COURT: That's strange. That's what you think what Mr. Morrissey said?

MS. HAGBERG: Yes, your Honor. If you would look at the first page of the document.

MR. VELIE: Your Honor --

THE COURT: Oh, you mean this cover --

MR. VELIE: I have an objection.

THE COURT: I'm sorry, not yet. The cover letter of V?

MS. HAGBERG: Yes, your Honor, SEK 898.

Q. Have you seen this letter before? Is it okay if I ask her --

THE COURT: I have. What part of the letter are you pointing me to?

MS. HAGBERG: I'm pointing to the second paragraph.

THE COURT: On the first page. "Please note that the management team is new at ADI. We've made many improvements to the company over the past twelve months. The inspection from FDA highlights some areas where we need to make additional improvements. We were gratified the investigator acknowledged many of the quality improvements that have been made." Where do you see the part about deficiencies in CAPAs?

MS. HAGBERG: Your Honor, the next paragraph says --

THE COURT: Okay. "Attached you will find a plan and status with regard to each of the items noted on the 483. The corrective action will be completed in the month of July 2011. However, we will monitor effectiveness in both July and August 2011 for observations three and four in order to verify the actions were adequate."

MS. HAGBERG: And one of the actions related to the CAPA.

Q. Did you hear Mr. Morrissey testify about what the purpose of this communication was?

A. I don't --

THE COURT: Okay, this is a silly line of questioning.

I guess I can just reread Morrissey and so could you and so could defense counsel. There's no point in asking her what she remembers him saying.

Q. Was the purpose of FDA's inspection in 2011 to determine the compliance of ADI in the prior years?

A. I don't know what FDA's motivation was for the inspection in 2011.

THE COURT: I think that's the answer. Thank you.

Q. I think when you testified about this document, and there was a plaintiff's exhibit --

THE COURT: What does "this document" refer to?

MS. HAGBERG: Just a moment, your Honor.

Q. Could you please turn, again, I'm looking at DX V. Could you please turn to the second page, SEK 899 and read the last sentence of observation 2?

THE COURT: I'll do it. "Corrective actions were taken but were addressed in a decentralized manner using other processes within the quality system."

MS. HAGBERG: Actually, your Honor, I am looking at page 899.

THE COURT: So am I.

MS. HAGBERG: Observation 2.

THE COURT: So am I. That was the last sentence on the page 899.

MS. HAGBERG: I am looking at the observation itself.

"Correction and prevention action activities and/or results have not been adequately documented. Specifically there is no corrective and preventive action documentation available prior to 7/23/10."

THE COURT: Yes? You asked that the last sentence on the page be read. It doesn't matter. That's what the observation was. Go ahead. That was the FDA's observation and this is Sekisui's response.

Q. And what does that mean to you, Ms. Kuehn?

THE COURT: I do not need the answer to that. This is plain English. I read it. I will not have her interpret plain English. It's my native language.

MS. HAGBERG: I believe that was a basis for her testimony.

THE COURT: I don't need her expert opinion -- experts testify to assist the Court. I have no trouble reading this plain English written in my native language.

Q. Could you look at DX AAA?

THE COURT: That's one of the ones handed up?

MS. HAGBERG: That was one of the ones handed up yesterday.

THE COURT: That takes a while to find.

MS. HAGBERG: I'm sorry, your Honor.

THE COURT: No, it's a whole pile here, may or may not be handy.

THE WITNESS: DX triple A?

MS. HAGBERG: AAA. It's the November 27, 2007 --

THE COURT: It wasn't one of those signature ones, was it?

THE WITNESS: I don't think so.

THE COURT: I have those in a separate place. It wasn't one of those.

THE WITNESS: I'm sorry, I don't think I have it in front of me.

MS. HAGBERG: I don't need to ask you about that document.

THE COURT: I don't think I have it either.

Q. Mr. Velie asked you about several documents that you did not recall receiving during the testimony yesterday, is that right?

THE COURT: Ones with signatures, right?

MS. HAGBERG: The ones with signatures -- there were that whole group that had no signatures.

A. I remember that.

Q. In your opinion do the existence of those documents with signatures affect all of the conclusions that you reached in your report?

A. Only to the extent that if there are other documents I did not see they give me a certain level of uncertainty, but in and of themselves those particular documents do not change my

opinions in my report, no.
Q. And many of your opinions are not impacted by the absence of documents or the fact that there might be additional documents, isn't that right?
A. That's correct. Many of my opinions are based on the documents themselves that I reviewed.
THE COURT: But that's the whole point. Your opinion is based solely on documents, right?
THE WITNESS: Yes, your Honor.
THE COURT: Of course. You didn't do interviews, you weren't there at the time, you didn't inspect buildings or laboratories, right?
THE WITNESS: I did interview, I did speak to some of the ADI employees who were employees but other than that, you're correct, it was based on a document review.
THE COURT: Who did you speak to?
THE WITNESS: I spoke with Hugh Fryer, Bhavna Gaikwad, Christine Silverstein and David Teicher.
THE COURT: Not, for example, to Leigh Ayres.
THE WITNESS: No. I did not speak to Leigh Ayres.
THE COURT: So the four.
THE WITNESS: Just those four, that's correct.
Q. But you relied on what you heard in your interviews with those employees, is that right?
A. Yes. It was very helpful. It confirmed what I believed I

was seeing in the documents themselves. It was helpful to confirm my interpretations of my findings.

Q. And did you ask them where relevant documents might be located at ADI?

A. I did.

Q. And did they give you additional documents when you asked for additional information from them?

A. Yes. When I asked about design history files specifically I was given access to the retrospective DHF's that Sekisui had, post acquisition ADI, put together during the remediation.

Q. And you heard the testimony of several witnesses, fact witnesses on behalf of ADI this week, is that right?

A. That's correct.

Q. And did that testimony support the conclusions that you reached --

THE COURT: I don't need her to characterize the testimony given at trial. That would be inappropriate. Credibility is for the Court to determine. I don't care what she thinks.

MS. HAGBERG: I'm not asking about the credibility.

THE COURT: You asked whether it supports her opinion. I'm not going to allow that. I'll decide that. Let's say Mr. Morrissey testified, let's say I don't find him credible. It can't support anything so I'm not interested in her view of any of the credibility of any of the witnesses she heard. The

objection is sustained. Please move on. I assume you are objecting, are you not?

MR. VELIE: Absolutely.

THE COURT: Absolutely and sustained. Now, can we have the next question?

Q. Are there, with certain of your findings do they rely on your review of specific documents that did not meet the criteria of particular provisions of the CFR?

MR. VELIE: Excuse me. Objection. That's been asked and answered.

THE COURT: Probably, but that's okay.

A. I'm sorry, can you repeat that question?

MS. HAGBERG: Could you read it back to her please.

(Record read)

A. That's correct.

Q. For example, management responsibility was one of the issues you addressed in Section 4.1?

A. That's correct.

Q. And wasn't your testimony yesterday based on the insufficiency of management review meetings?

A. That's correct.

Q. And additional documents wouldn't change that, would they?

A. No, that would not.

Q. And what about internal audits, one of the bases for your opinions was that individuals were auditing their own area, is

that correct?
A. That's correct.
Q. And additional documents, even if they hadn't audited their own area, wouldn't change your findings on that point, would it?
A. That's correct.
Q. And what about design control? You talked about deficiency in GEN 41 and the design control SOP and you pointed to specific incidences. Your opinion on that wouldn't change if you were shown another SOP that didn't have those problems, would it?
A. That's correct.
Q. And your opinion on manufacturing and in process control and that certain flow documents did not meet the definition of device master record, you were looking at specific documents to support that, isn't that correct?
A. That's correct.
Q. And that opinion would not change if you saw another document that maybe did meet that criteria, is that correct?
A. If a device master record meeting the criteria appeared, then, yes, it would change my opinion.
Q. But you didn't see any device master record and Mr. Velie didn't show you any device master record, is that correct?
A. That's correct.
Q. And what about acceptance activities? You relied on batch

records showing changing specifications without rationale, is that correct?

A. That's correct.

Q. So your opinion on acceptance activities wouldn't change based on seeing additional documents where they might have gotten it right, is that right?

A. That's correct.

Q. And what about non-conforming product and CAPAs? You talked about NCR's showing the use of expired materials and changing specifications. If you saw other ones where that didn't happen that's not going to change the opinion you made on non-conforming product, would it?

A. That's correct.

Q. What about complaint handling? You mentioned product incident reports that lacked a root cause of the analysis. If you saw another one that happened to have that, that wouldn't change the opinion that you made, is that right?

A. That is correct.

Q. And I believe that you said several times in your testimony that the regulations require compliance every time with every product. Is that statement still consistent and does that uphold the opinions that you included in your report that you just discussed?

A. That's correct. Compliance is required for all products every time without exception.

Q. And, again, it doesn't matter if you pass an audit or inspection, it's whether you comply, is that what laws require?
A. That's correct.
MS. HAGBERG: I have no furthers questions, your Honor.
MR. VELIE: Just a housekeeping detail and a very quick question.
RECROSS EXAMINATION
BY MR. VELIE:
Q. Ms. Kuehn, if you saw subsequent documents to documents that had faults in them correcting CAPAs or giving directions not to use a particular product, that might change your opinion with respect to those individual instances, is that correct?
A. It would depend on the content and I would take it into consideration, certainly.
Q. So context is all here, is that correct?
A. Because these systems are all integrated so heavily, yes, I mean, context would be very important.
MR. VELIE: Your Honor, the housekeeping detail, I would like to -- Ms. Kuehn and I shortened this morning's exercise quite a bit by my asking in bulk with respect to 13 audits, actually 14. The last one I put in I'm going to offer in evidence.
THE COURT: Audits and inspections.
MR. VELIE: Yes. I just want to offer them and give

her a chance to say, yes, that's what you and I were talking about.

MS. HAGBERG: Your Honor, I don't object to the documents coming in, but I don't know if he asked her about 13 or 14 different audits in her testimony.

MR. VELIE: If I have the number wrong that's okay. If there's no objection to the documents coming in we'll read it after the witness is off the stand and complete the record. Is that okay?

THE COURT: There's no objection to the actual audits and inspections coming in.

MR. VELIE: Exactly. I'd like to then read into the record what they are.

THE COURT: Yes. All Ms. Hagberg was saying she doesn't think we went over each of the 13 or 14 with the witness. That's what Ms. Hagberg said.

MR. VELIE: But I went over with the witness all of them in bulk I asked her with respect to all of the audits and inspections did you, and I'm not going to try to recreate the question --

THE COURT: She's saying you did not go over each one individually. You went over them collectively.

MR. VELIE: I did. I can have the witness say these are the ones she had in mind.

THE COURT: Well, you had in mind all of the audits

and inspections from '04 to '12.

THE WITNESS: To the extent they're the ones I reviewed for my report, yes.

MR. VELIE: Okay.

THE COURT: So the witness is done?

MR. VELIE: Yes.

THE COURT: Thank you.

(Witness excused)

THE COURT: Do you want to identify those now or later?

MR. VELIE: Yes. May we?

MS. BRILEY: DX 0, DX P --

THE COURT: Wait a minute, what is DX O?

MS. BRILEY: DX O is the Intertek report of the ISO certification in April, 2008.

DX P, the Intertek report of the ISO certification in April 2009.

DX N the Intertek report of the ISO certification in 2007.

DX L, the report from Intertek's document review of all of ADI's quality management system documents.

DX Q, the Intertek report of the ISO certification in June 2010.

DX R, the Intertek report of the ISO certification in March 2011.

THE COURT: Can I ask you to back up for a minute? You didn't give a date for DX L. You said DX L, the report of Intertek's document review of all of ADI's quality management system documents. That's of interest to me. What year was that?

MS. BRILEY: That was on March 24, 2006. It occurred prior to their first visit to ADI's actual facility.

THE COURT: Okay. Thank you.

MS. BRILEY: And DX T, the report of quality systems supplier audit by Seimans and that was on December 10, 2007.

THE COURT: Okay.

MS. BRILEY: Thank you.

THE COURT: Thank you.

MR. WHITNEY: Your Honor, just since we're doing some housekeeping matters, there have been several exhibits of prior witnesses that haven't been read into the record and I'd like to do that now.

THE COURT: Okay.

MR. WHITNEY: PTX 31, PTX 93, PTX 24, PTX 178, PTX 187, PTX 201, PTX 22, PTX 23, PTX 24, PTX 25, PTX 26, PTX 27, PTX 28, PTX 29, PTX 30, PTX 42, PTX 39, PTX 32, PTX 36, PTX 38, PTX 40. This is from the Ellis direct. PTX 240, PTX 241, PTX 242, PTX 243, PTX 244, PTX 245, PTX 246, PTX 247, PTX 248, PTX 249, PTX 250, PTX 251, PTX 253, PTX 273, PTX 7, PTX 8, PTX 56, PTX 67, PTX 236, PTX 60, PTX 71, PTX 74, PTX 73, PTX 72, PTX

76, PTX 77, PTX 81, PTX 17, PTX 18, PTX 19, PTX 54 and PTX 78.

THE COURT: All right. All of those are received as well as the entire list that was read by Ms. Briley.

(Defendant's Exhibits O, P, N, L, P, R and T received in evidence)

(Plaintiff's Exhibits 31, 93, 24, 178, 187, 201, 22, 23, 24, 25, 26, 27, 28, 29, 30, 42, 39, 32, 36, 38, and 40 received in evidence)

(Plaintiff's Exhibits 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 253, 273, 7, 8, and 56 received in evidence)

(Plaintiff's Exhibits 67, 236, 60, 71, 74, 73, 72, 76, 77, 81, 17, 18, 19, 54 and 78 received in evidence)

MR. WHITNEY: Thank you, your Honor.

THE COURT: So are we ready for the final plaintiff's witness?

MR. WHITNEY: Yes. Plaintiffs call Guy Erb to the stand.

GUY ERB,

called as a witness by the Plaintiff,

having been duly sworn, testified as follows:

THE COURT: Please be seated. When you're seated please state your full name, first and last spelling both for the record.

THE WITNESS: Guy, Guy-u-y, Erb, E-r-b.

THE COURT: Thank you.

MR. WHITNEY: I apologize for the weight of the binder, your Honor, this is financial documents for a damages expert. They're just bulky.

DIRECT EXAMINATION

BY MR. WHITNEY:

Q. Mr. Erb, what is your educational background?

A. I have a Bachelor's in economics, bachelors degree in economics from University of California at Berkeley and a certificate of a year spent under the auspices of NYU at the University of Madrid and a Master's in economics from the London School of Economics and Political Science.

Q. When did you graduate from the London School of Economics?

A. 1963.

Q. What did you do after graduate school?

A. I joined the U.S. Foreign Service and spent roughly two years in Washington as a Foreign Service officer and then I left that employment to become a member of the United Nations Secretariat where I spent the next seven years working on economic and financial issues for the United Nations. After that, I -- that included a year as a financial advisor to Central American Common Market and another financial assignment in southeast Asia.

I then joined a think tank in Washington, the Overseas Development Council, where I worked on trade and investment

issues for roughly five years and then joined the White House staff as a member of the National Security Council staff under Dr. Brzezinski. Prior to that I became deputy director of an independent agency, the U.S. International Development Cooperation Agency. I left that employment in 1981 and became a consultant and eventually formed a niche broker dealer called Lafayette Capital Corporation towards the end of the 1980's, where I worked until I received an assignment from Goldman Sachs. I worked on that issue for -- or those issues during 1990 and joined Goldman Sachs in late 1990, worked at Goldman in New York for four years and then in Mexico for four years, roughly five years, and then formed a company called Rapid Money Corporation in 2000 and worked in that company until 2005 when I went back to New York and began work at an expert services firm.

Q. What were your job responsibilities while you were at Lafayette Capital?

A. Mergers and acquisitions. We provided merger and acquisition services to corporations in the United States looking to invest or divest in Mexico and other Latin American countries and I occasionally worked for local clients as well on sell side assignments.

Q. What were your job responsibilities at Goldman Sachs?

A. Broad investment banking responsibilities including mergers and acquisitions, valuation of companies and investments by

Goldman's private equity arm and working with a lot of Mexican companies as potential candidates for equity debt or merger and acquisition transactions.

Q. Did you conduct any corporate valuations?

A. Yes. They were an integral part of what we did, even beginning very early on we advised the government on the value of companies they were privatizing such as the national phone company and major banks.

Q. After Goldman Sachs you said you went to Rapid Money Corporation. What were your job responsibilities there?

A. I was the co-founder, president and chief executive -- chairman and chief executive officer and had responsibilities that covered the entire scope of the company's operations. It was a regulated money service business.

Q. Did you have any opportunity to do corporate valuations with that position?

A. Yes. We valued our own company and were subjected to inquiries from companies interested in acquiring Rapid Money. We also looked occasionally at companies that we might acquire. In that process I became familiar -- of course I had worked on data rooms at Goldman but we had to prepare our own data room with regard to Rapid Money, and discuss letters of intent, possible purchase price for the acquisition of the company on a number of occasions.

(Continued next page)

BY MR. WHITNEY:

Q. Do you have any other work experience related to M&A in company evaluation?

A. Yes. I've worked on valuations as an expert assisting companies in the valuation of major corporate assets prior to allocation among different family interests or the sale of those assets.

Q. And I should have asked, did your work at Goldman Sachs include mergers and acquisitions as well?

A. Yes, of course.

Q. Where do you currently work?

A. At Berkley Research Group LLC.

Q. In what capacity?

A. I'm the director of the firm, and I provide expert and advisory services.

Q. And have you ever been retained as an expert witness before?

A. Yes. 10 or 15 times.

Q. In what fields?

A. Finance securities, international project financings and valuations.

Q. Has any tribunal ever determined that you were unqualified to be an expert witness?

A. No.

Q. What were you asked to do in this case?

A. I was asked to calculate damages related to the difference between the value of ADI as warranted and the value as delivered. I was asked to take this -- undertake this valuation from the prospective of a knowledgable investor who was aware of the breaches.

Q. And did you provide a report of your opinion?

A. I did.

MR. WHITNEY: Your Honor, I'd like to offer Mr. Erb as an expert in finance and economic analysis of mergers and acquisitions, including company valuation.

MR. KORTMANSKY: No objection to that, your Honor.

THE COURT: All right.

MR. WHITNEY: Your Honor, given that this is a damages expert, I thought some slides might help walk through some of the figures Mr. Erb used.

Could we have slide one, please?

Q. Mr. Erb, what methodology did you use to calculate damages in this case?

A. I used what's described as a benefit of the bargain value of ADI as delivered, as warranted compared to a value of ADI as delivered. The difference is the over pavement of the purchase price or the damages.

Q. And what do you mean by "value of ADI as warranted?"

A. That's the value that was established in the stock purchase agreement by the buyer and the seller, $25.5 million.

Q. And assuming that the representations and warranties and agreement are true?
A. Yes.
Q. And what do you mean by "the value of ADI as delivered?"
A. That was the value that we calculated not knowledgable investor would reach with an understanding of what the breaches were.
Q. And the difference you say is the overpayment of purchase price, is that correct?
A. Yes.
Q. And you consider that to be the benefit of the bargain?
A. Yes, I do.
Q. What did you understand the representations and warranty breaches in this case to be in your analysis?
A. Generally, that the company had warranted that it was fully compliant with FDA regulations, and that it had maintained under FDA standards all the material necessary to support the 510(k) application for Femtelle.
Q. And why did you look at the representations and warranties?
A. Well, they're the starting point of a buyer's assessment of the company. They provide a description of what he or she is buying, and they also provide a starting point for the planned operation of the company. In effect, they're an allocation of risk, the maker of the representation bears the risk of any inaccuracy.

Q. And why did you use the methodology you just identified?
A. I believed it was the appropriate way to calculate the damages in this case. It's bounded by the purchase price.
Q. How did you determine the value of ADI as warranted?
A. Again, we looked at the stock purchase agreement, that's the value in the stock purchase agreement.
Q. Let me turn to slide two, please.
This is a little more granular breakdown of your analysis. In general, how did you determine the difference between the value of ADI's warranted and the value as delivered?
A. Yes, top line really summarizes that statement. The next is redone -- we undertook three steps. First, we looked at the product Femtelle and the value of Femtelle had been allocated within a purchase price allocation provided by KPMG, and we --
THE COURT: When was that?
THE WITNESS: That was provided as of -- it was a document that calculated the value of Femtelle and other components of the transaction as of the transaction date.
THE COURT: So what was the date of the KPMG allocation document?
THE WITNESS: October 1st.
THE COURT: Of 2000?
THE WITNESS: 2009.
THE COURT: And the closing here was?

THE WITNESS: April 20th.

THE COURT: What year?

THE WITNESS: 2009.

THE COURT: I'm sorry. So the KPMG allocation document was six months later?

THE WITNESS: It was, but it was prepared as of the acquisition date.

THE COURT: What does that mean, prepared as of the acquisition date -- it was retrospective?

THE WITNESS: No. It took only -- all the dated documents in the PPA are dated prior to the transaction date. So the nature of any calculation of any allocation of this nature, it's done after the transaction. But only material that is about the company which is relevant to the period prior to the acquisition date is used.

THE COURT: Okay. But I am a little confused. So KPMG six months later says, I'm looking at documents that were before the closing.

THE WITNESS: Yes.

THE COURT: Based on that, I am determining --

THE WITNESS: That's right.

THE COURT: -- the allocation to Femtelle was X minimum.

THE WITNESS: That's right.

THE COURT: But it didn't do that before the closing.

THE WITNESS: It couldn't.

THE COURT: Well, it didn't.

THE WITNESS: That's right.

THE COURT: And, therefore, nobody relied on KPMG's opinion then.

THE WITNESS: No, but --

THE COURT: No.

THE WITNESS: -- that's true.

THE COURT: So it looks back at, analyzes preclosing documents and it attributes that dollar figure.

THE WITNESS: Yes.

THE COURT: Okay.

THE WITNESS: Allocates the total --

THE COURT: Yeah, I understand. Does it six months later based on preclosing documents. But it didn't do it preclosing, hand it to the parties and say rely on this, rely on our allocation.

THE WITNESS: That's right.

THE COURT: Okay. Go ahead.

A. So that was the starting point for step one, recalculated the value of Femtelle as delivered by examining what KPMG had done altering those, that work, and that gives us the --

MR. KORTMANSKY: Your Honor, may I just ask Mr. Erb to speak up a little bit?

THE COURT: Sure.

MR. KORTMANSKY: Thank you.

THE COURT: Try to use the mic.

THE WITNESS: I'll use the mic and defer with the pointer here.

THE COURT: Yes.

THE WITNESS: Step one, the net value of Femtelle is calculated in the purchase price, purchase price allocation minus our recalculation of the value of Femtelle, give us the over payment for Femtelle.

In step two we looked at the net value -- the value of current products in the purchase price allocation, recalculated value for current products as delivered. The difference is the over payment of current products. Those two steps were the first two parts to the analysis.

We then calculated the expected cost of remediation of the breaches and added that number to the recalculation of the, or the calculation of overpayment for Femtelle and the overpayment for current products.

Q. And you've been referring to the PPA as part of your testimony here. I'd like to put up exhibit PTX 48.

A. Could I have the book?

Q. Oh, yeah. Do you have a --

A. This is --

Q. -- exhibit binder?

A. This is Ms. Kuehn's binder.

Q. I'm sorry, could we get the witness an exhibit binder?

MR. WHITNEY: May I approach, your Honor?

THE COURT: Yes.

A. Yes, I have that.

Q. Is exhibit 48 the PPA you're referring to?

A. Yes, it is.

Q. And what is the purpose of the PPA?

A. This is a document prepared in the ordinary course of business by an accounting firm for accounting reporting and tax reporting by the buyer.

THE COURT: It says, we understand that Sekisui management would use our report for financial and tax reporting purposes.

THE WITNESS: Yes.

THE COURT: Okay. So that's the purpose.

THE WITNESS: Yes.

Q. It's not created for the purpose of litigation, is that correct?

A. That's correct.

Q. On what information is the valuation in the PPA based?

A. They had financial data on the company. They had other financial information on ADI. They had results of consultations with ADI management and with Sekisui management as well, and they used other materials in their calculations, material available as of the time of transaction on publicly

traded companies.

Q. And how do you know this?

A. It's stated in the PPA and the letter and elsewhere in the document.

Q. Can we look at SEK-341?

A. Yes. The scope of the analysis section 1.4.3 goes through the, in more detail what I just said. Part of it historical financial statements analysis of unaudited financial statements and other operational data and stock purchase agreement of course is the basis for the entire document. It takes the -- that gives them the acquisition price. And all these, this information is used in the preparation of the allocation of the fair values.

Q. And was the, were the projections used in the allocation in the PPA taken from pre-acquisition ADI management?

A. Yes, that's true. All the projections were based on material received from ADI.

Q. And ADI, you're referring to pre --

A. Pre-acquisition.

Q. Pre-acquisition?

A. Pre-acquisition management, yes. These were documents that had been prepared in 2008 in consultation with Crosstree, their financial advisor. And with some minor alterations, they're the same data that formed the basis of the initial period that was projected forward.

Q. And subsequently, was KPMG provided with this information after the transaction?

A. Yes, after the transaction, but the data was basically the same as had been prepared before the transaction.

Q. And how do you know this?

A. I've seen the record, and there is an e-mail that describes this process.

MR. WHITNEY: I'd like to bring up PTX-8, please?

Q. Is this the e-mail to which you're just referring to?

A. Yes.

Q. And could you flip to --

MR. WHITNEY: It's not Bates numbered, your Honor, because it was provided by Crosstree Capital, and they did not Bates number their documents.

Q. But I'd ask to turn to page two?

A. Yes.

Q. And this is an e-mail from Hideharu Kojima. You see that?

A. Yes, I do.

Q. Do you know who that is?

A. Yes. He is an employee of KPMG.

Q. And that e-mail states it's written to Jeff Ellis. Do you see that?

A. I do.

Q. And as we know from prior testimony, Jeff Ellis is the managing director of Crosstree Capital Partners, the

pre-acquisition ADI management's financial advisors?

A. Yes.

Q. It says, "We are currently working on a purchase price allocation assignment for Sekisui and as part of that we would like to understand some more detail of the basis for ADI projection numbers in the offering memorandum."

A. Yes.

Q. "We understand Crosstree helped ADI put that together. If it is okay, Takefumi Semba from a valuation practice copied here, would like to talk to you. Let me know if you can do that."

A. Yes.

Q. You see that?

Then if we go onto the later e-mails on the first page.

A. Sorry.

Q. You see that Mr. Semba writes to Mr. Ellis, "Hi, Jeff. I am Takefumi Semba at KPMG economic and valuation services. I asked Jose, let me know the contact information of Crosstree Capital. We are now engaging in the purchase price application of ADI for Sekisui. In our analysis, we need detailed projection of ADI. I found the information memorandum of ADI showed the five year projections, including the projections by each product category. We are wondering if projections provided by ADI's management are prepared by Crosstree's

people."

A. I see that, yes.

Q. Okay. And it goes on -- you can see the document. Mr. Ellis responds "Hi, Takefumi. Thank you for your e-mail. The projections were a collaborative effort. Crosstree compiled and analyzed historical unit volume, pricing and margins, and built a forecast model to project based upon these metrics. ADI then provided the assumptions for growth in each product line. We performed this exercise primarily with the company's former CFO, who has since left ADI, and with input from Richard Hart, CEO."

A. Yes.

Q. And then it concludes with an e-mail from Mr. Semba to Mr. Ellis that states, Hi, Jeff, thank you for your reply. I understand how the projections were built. As you mentioned, no current staff knows the projections and the assumptions, so we have had a little difficulty going forward with this work. However, we will have an opportunity to discuss this with Richard soon and he may be able to receive more detailed information." You see that?

A. Yes, I do.

Q. What did you rely on this correspondence?

A. Well, this shows two things about the preparation of the PPA. One, the consultations with preacquisition management and, two, that management had basically provided the material

for the projection going forward.

Q. And --

MR. KORTMANSKY: Your Honor, there is no evidence. The document speaks for itself.

THE COURT: It does.

MR. KORTMANSKY: Thank you.

Q. And did you compare the projections in the PPA with the preacquisition management's projections?

A. I did.

Q. And what did if you determine?

A. They are basically the same for Femtelle, and only slightly different with regard to the current products.

Q. And were you in the courtroom for the testimony of Mr. Takemura?

A. Yes, I was.

Q. And you recall any testimony regarding who provided those projections to KPMG?

A. Yes. He confirmed that --

MR. VELIE: Objection, your Honor. The testimony is the testimony.

THE COURT: Yes, it is, but it was several days ago. If he recalls it, I'll listen. If you think it is inaccurate, he'll tell me. Go ahead.

A. Yes. He confirmed that the Femtelle projections had been provided by Mr. Hart and that they had consulted on the current

product as well.

MR. KORTMANSKY: I just object to --

THE COURT: Pardon me?

MR. KORTMANSKY: I withdraw it.

THE COURT: All right.

Q. And why did you rely on the PPA for your determination of the value of ADI as warranted?

A. PPA was a roughly contemporaneous document to the transaction. It relied on data from ADI financial, from ADI financial data prior to transaction date. It relied on consultations with both management of ADI, preacquisition management of ADI and Sekisui. It was prepared by a respected accounting firm and was an unbiased third-party assessment of the allocation, appropriate allocation of the assets acquired by the company, and it gives us a fair value for each of those, each of those components.

Q. What do you mean by "fair value?"

A. Fair value is a term that refers to the value set by a willing buyer and a willing seller.

Q. And where in the PPA does it include the figures regarding the value of ADI's assets?

A. There is a table in the letter that does that.

Q. Would you point us to that, Mr. Erb? You have your binder as well if you like to --

THE COURT: It's on 334.

THE WITNESS: Yeah, it's on 334.

THE COURT: I see it. It says, current products. It says in process R&D. Under process R & D it says Femtelle, it gives a number.

THE WITNESS: That's right.

THE COURT: Right.

Q. So, generally speaking, how did you use this data?

A. Well, this was the basis of our calculations of the value as warranted.

And if I could point out a few of the important numbers on this document. First, the purchase price --

THE COURT: Anyway, I see it, 25.5 million.

Q. Go through the numbers that you relied on Mr --

A. The next number I would call your attention to, your Honor, is the present value of the earn out payments. That includes the milestone payment of 4,560,000. The next number I would call your attention to is total current product allocation, 9,900,000 and, as you just said, your Honor, the Femtelle value of $12,213,000. These are all their estimated fair values as of the time of the transaction.

I would gave an illustration of how we used this table. If you look at the present value of the earn out payments, the second line, and the in process R&D value for Femtelle, looking at the second number 12,213,000, is the present value of the fair -- of the stream of payments related

to Femtelle. However, those earnings and those cash flows generate an obligation that contingent liability on the part of the buyer to pay the seller, the present value of 4,560,000. So if you subtract that obligation of the seller from the value of the stream of payments, you get the value of Femtelle as warranted, which is $7,563,000.

Q. And again this valuation is bounded by the purchase price, correct?

A. That's correct. We started with the SPA's purchase price.

Q. Bounded by the value of the company as agreed upon by the parties?

A. That's correct, in the SPA.

Q. Generally speaking, Mr. Erb, how did you determine the value of ADI as delivered at the time of the closing, assuming breaches of the applicable representation and warranties?

A. I took the perspective of a knowledgable investor who was aware of the breaches and who was valuing the company as of the transaction date looking forward, but not using hindsight to -- not using any subsequent events following the transaction date.

Q. On what information did you base your determination of the actual value?

A. Well, we started with the -- as warranted you mean?

Q. No, as delivered.

A. Oh, as delivered. We based our information on ADI financial information and business records. We consulted with

the employees of the company. We looked at, of course, the PPA as a starting point, and we reviewed other material in the case record.

Q. Did you consult with any experts?

A. Of course. We looked at -- the knowledgable investor was a person who would have either knowledge of the relevant sector or be familiar with the process of consulting experts where there were gaps in his or her knowledge. This is the process I --

THE COURT: Why do you use a hypothetical, not reasonable investor instead of Sekisui?

THE WITNESS: Well, Sekisui's value was as warranted.

THE COURT: No, I don't mean that. You could have said what would it have been worth to Sekisui if they had known.

THE WITNESS: We did ask -- sorry.

THE COURT: As opposed to a reasonable hypothetical investor.

THE WITNESS: Yes. We did ask Sekisui what they would have concluded had they not been aware of the breaches. But it was my understanding that the use of the knowledge of investor construct instrument was consistent with Second Circuit law.

THE COURT: Oh, okay. That's why you chose it.

THE WITNESS: On advice of counsel, yes.

THE COURT: Oh, okay.

MR. KORTMANSKY: Your Honor, we object to the extent that he's relying on statements from witnesses that testified here and for which they didn't provide any testimony related to --

THE COURT: I'm sorry, you are going so fast, I don't understand you.

MR. KORTMANSKY: I apologize.

THE COURT: Say it again.

MR. KORTMANSKY: We object to the extent that he is relying on information received from witnesses that testified here, and that did not testify regarding the areas on which he provides his basis.

THE COURT: I don't understand anything you just said. I really tried, but it was incomprehensible.

MR. KORTMANSKY: I can give you an example. Mr. Takemura was here.

THE COURT: Okay.

MR. KORTMANSKY: Mr. Takemura when he testified, for example, I don't want to interrupt Mr. Whitney's representation.

THE COURT: You are interrupting. That's okay.

MR. KORTMANSKY: But he testified regarding the then current products, which is a portion of Mr. Erb's report, and he said -- he gave his reasons why he thought the company lost money, and those reasons were all prospective reasons. We

discovered the breach. We realized that we wound up having to pay money to remediate. We suffered reputational harm. We actually had to pull products, and as a result based on what was estimated in the PPA, we lost $15 million. That's a prospective look, and that actually is the specific report that Mr. Erb originally issued, prospective look which he withdrew. This look is going backwards. He's saying what would an investor had done at the time. Mr. Takemura didn't testify about that at all.

THE COURT: Okay.

MR. KORTMANSKY: So to the extent that Mr. Erb relies on Mr. Takemura telling him what they would have done, that's all hearsay, that's all improper under Rule 703 to testify about it now.

THE COURT: Hearsay? I don't know what you're talking about. What's it got to do with hearsay?

MR. KORTMANSKY: Well, Mr. Erb is relying on statements from Mr. Takemura which are out of court so they're hearsay and he's using them to rely --

THE COURT: Wait. What out of the court? I thought you said testified here.

MR. KORTMANSKY: He testified here regarding one set of reasons why he thought they actually lost money.

THE COURT: Prospective reasons.

MR. KORTMANSKY: Prospective reasons. But Mr. Erb I

understand is saying that he talked to Mr. Takemura regarding what he would have thought.

THE COURT: But if that's in his report, an expert does research and reviews documents and interviews people and forms an opinion. As long as you know the bases of the opinion, that's okay. He's not summarizing their statements per se. But he's saying the basis for my opinion included those who I interviewed, just like the previous expert said I interviewed four people of the company. I didn't hear any objection. She named which four she spoke to and it was part of the basis of her opinion. Most of it was based on documents to be sure, but she also interviewed four people. So he says my opinion was based on not only all the records I reviewed, but I spoke to certain executives or employees of the company.

MR. KORTMANSKY: The difference, your Honor --

THE COURT: No surprise so you, it's no surprise to you. You must have known in the report that he spoke to people.

MR. KORTMANSKY: Of course he can speak to people, and of course he relied on those out-of-court statements for preparation of the report. The issue is whether under Rule 703 he can testify to what those statements actually were.

THE COURT: But he didn't testify to the actual statements. I thought he just said that that's one of the things that supports his conclusion. I don't think he

testified here chapter and verse as to what Mr. so and so said.

MR. WHITNEY: He didn't, your Honor. And of course as your Honor's I'm sure aware, Rule 703, an expert's perfectly allowed to rely on --

THE COURT: Do I need an echo? I said --

MR. WHITNEY: I'm sorry.

THE COURT: I said he interviewed people, he relied on that, as well as documents he reviewed. What he couldn't do is say, and I'm here to tell you everything -- is it Mr. Takemura? Here's what he said to me, I tape recorded what he said, he said X Y and Z. He can't do that, but he's not doing that.

MR. KORTMANSKY: With that, your Honor. Thank you.

THE COURT: Yes.

MR. WHITNEY: And, your Honor, I would just say that there are allowances for -- not that necessarily needs to happen here, but there are allowances for an expert to disclosing the data even if it is hearsay as long as the probative value outweighs the prejudicial effect. So it's not per se excluded from testifying about that.

Q. Okay. I'm sorry, Mr. Erb, you were talking about the basis for your analysis. Did you -- first of all, you're saying we. Did you have a team as well?

A. I did. But I approached this task of course as an expert in mergers and accusations, so I relied on what I learned over the years in my education and training and my experience in

mergers and acquisitions and formed my conversations with people and my analysis of the data.

Q. If we can turn to slide three, please?

What did you conclude were the damages to Sekisui for the representation and warranty breaches?

A. The damages were $12.18 million.

Q. And could you walk us through this chart?

A. Yes. Let me start, your Honor, by pointing out the top number, 25.36, that's slightly different than the 25.5 because there was some cash in the company which reduced that amount. So we start with a net value there. We removed the value of the cash.

THE COURT: I'm already confused. I'm already confused. It says "as warranted" is the name of that column, right?

THE WITNESS: Yes, that's right.

THE COURT: Where did Sekisui warrant that Femtelle had a value of 12.2 million, where did it warrant that?

THE WITNESS: Sekisui --

THE COURT: I'm sorry, did I say Sekisui? ADI.

THE WITNESS: No, they did not.

THE COURT: Oh.

THE WITNESS: This is the result of the analysis in the purchase price allocation that gives a contemporaneous estimate of the allocation.

THE COURT: Oh, so it's not as warranted by ADI.

THE WITNESS: Well --

THE COURT: It's your valuation based on all your records you reviewed, that that's the allocation that you think was made at the time, but it's not warranted.

THE WITNESS: Well, we understood the purchase price to be starting point, and the value of the company as warranted, the purchase price.

THE COURT: I understand the purchase price for sure is 25.36 million. All I'm quarreling with you about is I don't know there was a warranty as to the value of Femtelle.

THE WITNESS: The individual components, I don't believe there was.

THE COURT: Right. I think to the contrary, I think there's careful language, I think in the SPA that says something about you can't promise you anything as to what individual things are worth, something like that.

THE WITNESS: That was --

THE COURT: I may have it wrong, but.

THE WITNESS: Regarding projections, yes, that's right.

THE COURT: What is it?

THE WITNESS: The projections in -- I think there's a joinder that ruled out any information prior to the SPA.

THE COURT: I don't know. I'm sure it will come out.

I just wanted to quarrel with the word as warranted. It certainly wasn't warranted by the seller, ADI, that Femtelle had a value of 12 million, right? That's not warranted by the seller.

THE WITNESS: Correct.

THE COURT: Okay.

Okay, so I understand now this is the breakdown of the purchase price based on your analysis and primarily relying on KPMG's allocation.

THE WITNESS: That's right.

THE COURT: Okay.

THE WITNESS: So first bar is the value allocated to Femtelle. And as I explained, that's the difference between the --

THE COURT: Yeah, I got this.

THE WITNESS: Okay, fine. This is the value.

THE COURT: Allocation minus the stream of income, I understand.

THE WITNESS: Okay.

THE COURT: On the earn out.

THE WITNESS: The current products, as I stated, the bottom bar is everything else in the company assets inventory that doesn't change in our analysis. We're only looking at the first two components of that bar.

I then show you the results of step one and step two

where we value Femtelle as delivered at $625,000 and value the current products at $6,230,000 value that results of the company from step one. And step two is $14.57 million. And we then added the calculation made of the remediation expenses of, expected remediation expenses of $1.4 million bringing the value of the company as delivered to $13.17 million and the overpayment, as I mentioned before, $12.18 million.

Q. And when you say the value is warranted just to clarify, you're referring to the components, the relative value as the company was warranted in the SPA, is that correct?

A. That's correct.

Q. Turn to the next slide, please? Let's look at the analysis step by step.

A. Well, this repeats what I said, and I believe --

THE COURT: It does, and I fully understand it.

A. Okay, that's fine.

Q. So now let's talk about how you derived some of these numbers. I believe you testified about --

THE COURT: I don't need any more on this slide. That would be a waste of time. I got that slide.

MR. WHITNEY: Well, your Honor --

THE COURT: He testified to every word on that slide. Please, I don't have time to waste.

MR. WHITNEY: Okay.

THE COURT: That slide was fully covered. He

explained it. Don't you think you did?

THE WITNESS: Yes.

THE COURT: I do too. Okay.

Q. You testified that you valued the Femtelle as delivered at $625,000?

THE COURT: Mr. Whitney --

MR. WHITNEY: I'm just going to ask him how he derived, he got that number?

THE COURT: How he got the 625?

MR. WHITNEY: Yes.

THE COURT: All right.

MR. WHITNEY: I thought you'd want to know that.

Q. How did you determine the $625,000 figure?

A. At the time of the transaction, there were historical Femtelle sales. These were sales by ADI U.S. and sales through the company's German subsidiary.

Q. And why did you rely solely on existing Femtelle sales?

A. Well, they were a fact, they were historical sales that I believe should be taken into account.

Q. And why did you not value any IVD sales for Femtelle in the U.S.?

A. IVD sales, that is with FDA approval, the knowledgable investor considering everything that he knew with knowledge of the breaches, could not reasonably conclude that there would be Femtelle sales; and specifically that that judgment is based on

my consultation with an expert in the field, Mr. Ulatowski, who is the sort of expert, industry expert or subject matter expert that a knowledgeable investor would consult.

Also with awareness of the breaches, I would say that the knowledgable investor knew of the failure of the 2007 application to get approval from the FDA, and he would have Mr. Ulatowski's view that the 2009 application, which was pending at the time of the transaction date, would also fail; therefore a reasonable conclusion that I would draw of the knowledgable investor is is that the only sales that I could rely on were those that historically were in the company's books and records.

Q. Did you look at any other information for your determination other than what you just testified to?

A. Yes, there were e-mails that I reviewed.

Q. I'd like to call up PTX-11?

A. Can you expand that a little bit.

Q. You also have it in your binder, Mr. Erb.

A. I do, yes, but it's small there too, yes.

Q. Okay, sorry. Is this one of the e-mails on which you relied?

A. Yes, it is.

THE COURT: I'm sorry, who is Lum Shapiro?

Q. I'm?

MR. WHITNEY: Sorry, your Honor. We're on PTX-11?

THE COURT: I think I am.

A. Yes, this is an e-mail from Marie Louise --

Q. I'm sorry, you're right.

THE COURT: I still said, who is Lum Shapiro?

THE WITNESS: I have no idea, your Honor, correspondent of Mrs. Hart. The e-mail address she's replying to a message from Mrs. Hart. It's from one --

THE COURT: I know. I don't know why I should --

THE WITNESS: We have --

THE COURT: -- be interested in Wanda Toff's statement. I don't know who she is.

THE WITNESS: We're not, your Honor. We're interested in the message from Mrs. Trudel-Hart.

Q. What specifically --

THE COURT: So what -- wait, wait, wait. Slow down. So I guess I'm just going to eliminate the -- I would if the pen worked --

THE WITNESS: Here.

THE COURT: That's okay, I got lots of them. I'll find one that works. You know the government, half the pens don't work.

So, in any event, let's get rid of that e-mail.

So you want the one that starts with, Dear Wanda?

THE WITNESS: Yes.

THE COURT: It ends with thanks, Louise?

THE WITNESS: Yes. I'm looking at specifically the second paragraph.

THE COURT: Okay. Luckily?

THE WITNESS: The second sentence. We have, in 20 years not been able --

THE COURT: I don't have it -- oh, yes. We have in 20 years not been able, not having the funds and resources to get it through the FDA. They indicated they wish to come back and visit and talk and who knows, the Japanese are very hard to reach read.

THE WITNESS: I'm referring merely to the second sentence, your Honor.

MR. WHITNEY: I believe the full paragraph actually would give that sentence context.

THE COURT: I think so too. Luckily, a Japanese company is now looking into a marketing agreement for one of our products, Femtelle. We have in 20 years not been able, not having the fund resources to get it through the FDA.

Q. Why did you rely on this e-mail?

A. This is a statement by one of the owners of the company, and it appears to be a judgment that they have not succeeded in getting approval for Femtelle.

Q. Okay, I'd like to turn your attention to PTX 195, please?

THE COURT: Of course, a purchaser knew there had not been approval for Femtelle, right?

THE WITNESS: Yes. But my point is that it has a long history.

THE COURT: The purchaser certainly knew it had not yet been approved. There are always risks prior to approval.

THE WITNESS: That's true.

THE COURT: Now what do you want turn to now?

MR. WHITNEY: PTX-195.

THE COURT: 195. Okay, one minute. There is a lot of paper flipping. All right.

THE WITNESS: I would comment on the paragraph after the list of regions begins since 1990.

THE COURT: Wait a minute. This is from Mr. Hart.

THE WITNESS: Yes, this is from Mr. Hart.

THE COURT: Okay.

THE WITNESS: On --

THE COURT: On February 11th, 2009 right.

THE WITNESS: Preacquisition.

THE COURT: Right. And he says, since 1990, ADI has invested between four to $5 million into Femtelle. So I consider that when possible in a licensing agreement for Femtelle and the trademark, we should seek some immediate return on capital investment, for example, a one time licensing fee for example.

A. Yes. We have two points here; that the investment in Femtelle has been considerable without success and he's seeking

immediate return on that capital investment.
Q. And this would also be bounded by the knowledge that you discussed with Mr. Ulatowski, is that correct, of the --
A. Background, yes, that's right.
THE COURT: Again, would you remind me what that was again?
THE WITNESS: Well, Mr. Ulatowski's judgment was that the pending application would fail.
THE COURT: Right. Okay.
Q. And if we look at PTX-12?
THE COURT: Oh, dear. That means flipping --
MR. WHITNEY: Oh, sorry.
THE COURT: -- through the book. All right.
A. Here we want to look at the second message from Mrs. Trudel-Hart beginning, hello Chantal, and we look at the second sentence, latter part of it. Our Femtelle is still not approved by FDA and we need more clinical studies which we can not afford. The date of this is January 25th, 2009.
Q. Why did you rely on this, Mr. Erb?
A. Well, here we have an indication that more clinical studies are needed, which would be consistent with Mr. Ulatowski's view.
Q. All right. You can take this down this e-mail.
THE COURT: I'm sorry.
MR. WHITNEY: I was about to ask a question. I'm

sorry. I was just checking my notes.

THE COURT: Oh.

Q. Did you rely on anything else in making your determination?

A. I'm not sure I follow the question.

Q. I'll withdraw the question.

Why did you consider the information that you did?

A. Well, the information in the PPA and the e-mails you mean, is that --

THE COURT: That's right, that's his question.

Q. Yes.

A. Yes. Well, I had to form a judgment as to what a knowledgable investor would conclude about the prospect for Femtelle. And having reviewed this and the information from Mr. Ulatowski, the history of the Femtelle 2007 application and the judgment that clinical trials were still needed, and that the 2009 application would fail, I concluded that a reasonable investor could not have any basis for conclusion, other than that the Femtelle sales would be zero going forward, the IVD sales would be zero going forward.

Q. Yet you still valued Femtelle at $625,000, is that correct?

A. That's correct.

Q. Why is that so?

A. Because there were historical sales of Femtelle, and we felt that we could project those forward and calculate a present value of those sales.

Q. How did you do that?
A. We looked at financial data on company records that showed the sales of Femtelle and undertook several calculations to reach an estimate of what Femtelle, total Femtelle historical sales were prior to the acquisition.
Q. And did you discount those sales to the present value?
A. We did. We -- any -- that's following the procedures in the PPA which had done the same thing, projecting forward and then discounting them back to the transaction date using a discount rate.
Q. What is a discount rate?
A. A discount rate is a rate that embodies the time value of money and risk. Time value money referring to the fact that a dollar tomorrow is worth less than a dollar today, and the PPA calculation included discount rate for current products of 17.4 percent, and we used that because these were historical sales, not a product in research and development. And we used that same discount rate of 17.4 percent which has been calculated in the PPA.
Q. Do you know why KPMG chose that discount rate in the PPA?
A. They explained their procedures. They calculated the weighted average cost of capital and the internal return, rate of return, and added a risk factor to get to 17.4. It's all laid out in PPA.
Q. And what information did you rely on for the historical

Femtelle sales data?

A. We had company records.

Q. I'm going to identify the company records -- well, let's turn to PTX-196. Actually, let's -- all right. Well, unfortunately, the order of doing this requires flipping through the bulky documents, your Honor. I apologize, but let's turn to PTX-196?

A. Yes. This is sales by product by ADI for fiscal years 2005 through 2008 with a trailing 12 month figure that runs through September 30th, 2008.

If you scroll down, you'll find a category saying oncology. And there we have the historical sales by ADI U.S. in the period prior to transaction. These show stability of sales, roughly $250,000, your Honor, and they give us the basis for the ongoing calculations. These sales are sales by the U.S. company which include sales at a wholesale level to the German subsidiary. They have to take a couple of other steps to get to the total Femtelle sales.

Q. Okay. What were those other steps?

A. Well, because these are wholesale transactions, the part that went to ADG, we have to separate those out and come back to ADG's retail sales.

Q. Can we look at PTX-51, the bulky document?

What is this document?

A. This is invoice-based data, which includes data prior to

the transaction, and allows us to separate out the sales by U.S. or ADI U.S. I should say, to the German subsidiary which we did.

Q. Can you just summarize for the record ho used this data?

A. We had invoices for the individual sales by ADI U.S. prior to the transaction for a period I think it's January 2008 through the transaction date, and that allows us to take that invoice data as the wholesale sales and remove it from the first table we looked at -- I'm sorry -- and we add up the sales, that's not correct, we add the sales on this table to get the monthly data by U.S. ADI, only within the United States, not non U.S. sales.

Q. Data for Femtelle?

A. Data for Femtelle.

Q. And did you did you do any other steps in your calculation?

A. One more. We had to calculate the sales at retail level by ADG.

Q. And could we turn to exhibit 214, PTX-214? What is this document?

A. This is sales monthly in euros by ADG, which allowed us to get the retail sales, which we then added to the figure for U.S. sales only, after a conversion from euros to dollars.

Q. Do you have any other steps in your calculation, or is that it?

A. Those were the -- that's it -- for the Femtelle historical

value.

Well, what we then did, having these monthly numbers, we took the highest 12 month figure prior to the transaction, used that as the basis for the transaction. That number was $408,000, including the retail sales, and we projected that forward and then discounted it back as described.

Q. And was all of this information available prior to the transaction?

A. Yes.

Q. And as a result, you made your determination of a $625,000 valuation for Femtelle as delivered, is that correct?

A. The present value of the cash flows as we calculated was $625,000.

Q. Okay. So now let's look at step two of your analysis, if we can, slide five.

A. This refers to current products, your Honor, and it repeats the number that I mentioned earlier, the over payment of repurchase price, $3,758,000.

Q. And you testified that the 9.99 million was from the PPA, correct?

A. Yes that's right.

Q. How did you determine the value of as delivered by -- well actually I should step back. What are current products?

A. Everything except Femtelle that's sold by the company.

Q. And how did you determine the value as delivered of current

products?

A. Here, again, a knowledgable investor with awareness of the breaches and their likely impact on total sales. Taking that into account, I concluded that the knowledgable investor would give the company credit for the sales levels achieved prior to the transaction and would be able to maintain those sales going forward for the period 2009-2013. And that's what we did.

We calculated the sales of current products prior to the transaction on a trailing 12 month basis, picked the highest number of those figures, which was 10,153,000 for current product sales. We then kept that number constant through 2013, and from that point on reverted to the growth rates projected by KPMG. And this, this number when brought back to a present value using the discount rate of 17.4 gives us the value as delivered of 6,232,000.

Q. Why did you keep the sales levels constant for current products through 2013?

A. That was my judgment, it could be supported by an awareness of the breaches and awareness of potential sales of the company, faced with the impact of the breaches on the company sales.

Q. And what information did you base that opinion on?

A. Well, I asked Mr. Takemura what he would have expected those sales to be with knowledge of the breaches, and I consulted --

MR. KORTMANSKY: Your Honor, this is precisely my objection I was making earlier.

MR. WHITNEY: He's stating the basis for his opinion, your Honor.

THE COURT: Yes, I realize that.

A. And I also consulted an expert in the field as to the scope of the breaches of the reps and warranties regarding the operation of the company and how they would affect, how they could affect sales going forward from the transaction date, that was Ms. Kuehn, who was subject matter expert of the sort that a knowledgable investor would consult. And with that explanation in hand, I reached the conclusion that a reasonable investor could look at the sales achieved and maintain that level until growth was restored.

THE COURT: Okay, I just want to read the answer to myself.

(Pause)

THE COURT: Okay.

MR. WHITNEY: And we don't have to do this, because I know it would draw an objection, but if your Honor would like to hear, if your Honor find it probative, I could ask Mr. Erb the substance of his conversations with Mr. Takemura. I know it will raise an objection from counsel. We don't have to do it, make the a little record a little more robust, or we could just rely on the fact he discussed it?

THE COURT: That's fine. I mean, there is no need to do it.

MR. WHITNEY: Okay, that's fine.

Q. Did you see any evidence in the record about the content of the customer base for the company?

A. Yes. In one of the aspects, which was highlighted in the preacquisition consideration of this company, was the fact that 90 percent of its customers were repeat customers, and this makes more dramatic as it were the possible impact on customers of the breaches of reps and warranties, loss of customers could be reasonably anticipated as a result of the breaches.

Q. Why did you rely on this information in making your determination of the value of current products as delivered?

A. Well, I believed it was the reasonable conclusion that a knowledgable investor with knowledge of the breaches would come to.

Q. And what financial information did you use to calculate the value of current products as delivered?

A. Well, the first step which we did for both Femtelle and current products was to replicate the KPMG analysis in the PPA, so we knew we were on all fours with their model.

We then recalculated the model as developed by KPMG to reach the flow of, cash flows -- future cash flows and discounted those backward.

Q. Call up exhibit PTX-50, please?

What is this document?

A. This is example of the business records that we used to support our calculations of current products 12 month basis. These are consolidating income statements from the company.

Q. For what year?

A. This is year the period ending June 2008. There are monthly data behind this page.

Q. Did you rely on this information to your calculation?

A. I did, yes.

Q. And did you rely on any other financial data?

A. We had some more financial data. There's an exhibit which illustrates that.

Q. Can we call up PTX-234, please?

MR. WHITNEY: Your Honor, it's essentially the same.

A. Well, different time period.

Q. I know, I was avoiding having to turn the binder if necessary.

What is this document, Mr. Erb?

A. Again, these are preliminary consolidating income statements on a monthly basis which allow us to calculate through March of 2009, and we also used it to calculate the ten days after the transaction date.

Q. What did you do with this data, how did you make your calculation?

A. Well, we have total sales here and we subtracted from the

total sales the Femtelle sales that I just mentioned.
Q. And then you discounted the values back?
A. That's right. Same procedure, same methodology. We just maintain consistency with the PPA.
Q. And that's how you derived your figure, the value of current products as delivered?
A. Yes.
Q. Let's turn to slide six? This is step three. What is step three?
A. We have, we now have the calculation of the overpayment for Femtelle and current products, 10.783 million, and we calculated the expected remediation costs of 1.4 million to reach our total overpayment.
Q. Why is it not double counting to --
MR. KORTMANSKY: Could we have the basis for that last cost -- he's provided the basis for all his other --
THE COURT: 1.4 million?
MR. KORTMANSKY: Yes, your Honor.
MR. WHITNEY: We are getting to that, your Honor.
Q. Why isn't the 1.4, inclusion of expected remediation cost, not double counting with your prior analysis?
A. Well, there are two separate issues. One is the effect of the breaches and one is the expected cost of remediating the breaches.
Q. And what did you base that expected remediation cost of

$1.4 million on?

A. Again, I consulted Ms. Kuehn whose report had indicated that the cost of remediation would be lengthy and protected I think was the phrase she used, and I asked her to explain that and she told me that in her estimate it would be roughly two to $3 million over two to three years.

MR. KORTMANSKY: Your Honor, this is precisely the information that was excluded yesterday, from Ms. Kuhen's testimony. She was not permitted, it was not in her report.

THE COURT: That's true.

MR. WHITNEY: It was in Mr. Erb's report, your Honor.

MR. KORTMANSKY: I understand it was in Mr. Erb's report, but that's hearsay statement. And this is Mr. Erb now trying to put forth Ms. Kuehn's expert opinion through Mr. Erb?

MR. WHITNEY: Basis for his analysis, your Honor, in his report.

THE COURT: I think the bottom line of the case law is he can do that, but if the information he relies on is not credible, neither is his opinion. So the real attack is on Ms. Kuehn's ability to make this projection.

MR. KORTMANSKY: Thank you, your Honor.

Q. Okay. But this is what you relied on, Mr. Erb, is that correct?

A. That's correct.

Q. Okay. And is there any other testimony that you heard that

has confirmed that view?
A. Well, Mr. Morrissey had a similar estimate in his testimony, and Mr. Takemura testified that remediation had gone on for two years and in fact was still continuing. So reasonable basis to conclude there were costs of remediation although he didn't specify.
Q. And how did you use this information?
A. Well, here we took that estimate and applied it within our model, we applied $1 million of the estimate to 2010, 1 million to 2011, and 1 million to -- excuse me -- 500,000 to 2012. That was part of our model. So those numbers were also discounted along with all the other discounting of the cash flows. So that's why we say 1.4 million rather than 2.5.
Q. Why did you discount it?
A. Because there are future expenses, and to maintain consistency the model and our approach that a knowledgable investor would take, and because in any estimate like that there are uncertainties. And so the discount rate allows for the risks that expenses might be less.
Q. And what discount rate did you use?
A. Same as we did before, the 17.4.
Q. Why did you do use that rate?
A. Consistency with the PPA, and seemed to be a reasonable rate, lower rate would result in higher damages.
Q. And if we can turn to slide seven, I believe this

summarizes your testimony here today?

A. That's correct. We reviewed this before number are the overpayment for Femtelle of roughly seven million, overpayment for current products of 3.758, and the 1.4 million add up to 12.183.

Q. Does this damages analysis include a calculation of prejudgment interest?

A. No, it does not.

Q. Does it include a calculation of attorneys fees?

A. No.

MR. WHITNEY: No further questions, your Honor. Would you like me to read into the record the exhibits we just discussed?

MR. VELIE: Your Honor, may I take a brief break while that's happening.

THE COURT: Sure, I think we all will, before the cross-examination anyway. So if you want to wait for this witness exhibits, that's fine or you can start.

MR. VELIE: Thank you.

MR. WHITNEY: You know what, your Honor, let me take the break to make sure I have all the exhibits. I'll do it after the break.

THE COURT: Okay.

MR. WHITNEY: Thank you, your Honor.

THE COURT: All right, so let's reconvene at ten

minutes ten after 12:00.

(Recess)

(Continued on next page)

MR. WHITNEY: Your Honor, I'm going to read the exhibits into the record?

THE COURT: Sure.

MR. WHITNEY: PTX 8, PTX 11, PTX 12, PTX 48, PTX 50, PTX 51, PTX 195, PTX 196, PTX 214 and PTX 234. I think they're already in the record but PTX 3 and PTX 5 as well.

THE COURT: They're all received.

(Plaintiff's Exhibits 8, 11, 12, 48, 50, 51, 195, 196, 214, 234, 3 and 5 received in evidence)

MR. WHITNEY: Your Honor, we've marked a copy of these slides as PTX 278.

THE COURT: That's just for demonstrative. It's not evidence in itself, but as a demonstrative exhibit. I'll take a copy of the slides. All right, Mr. Kortmansky?

MR. KORTMANSKY: Thank you, your Honor.

CROSS-EXAMINATION

BY MR. KORTMANSKY:

Q. Mr. Erb, the stock purchase agreement, it did not assign specific values to individual assets, did it?

A. No.

Q. But your methodology was to assign a portion of the purchase price in each asset that was acquired, is that correct?

A. That's the PPA information, yes.

Q. But that's also what you did?

A. I didn't assign them. I took values as calculated by KPMG.

THE COURT: Right, but he's saying you used those numbers to do your calculations.

THE WITNESS: That's correct.

THE COURT: So you, too, assigned in that sense.

THE WITNESS: Yes.

THE COURT: The work was done by somebody else but you accept it.

THE WITNESS: That's right.

Q. And you used the KPMG report because you believed that document provided an independent third party valuation, correct?

A. Yes.

MR. KORTMANSKY: Can we actually turn to that? I believe it's Exhibit 48.

THE COURT: Yes, he knows. Page 2. It says, "We understand that Sekisui management will use our report for financial and tax reporting purposes." He knows that.

MR. KORTMANSKY: And I'm sure he also knows on page 45 of PTX 0048-45, page 45 of the exhibit.

Q. Mr. Erb, you're also aware of the nature of opinion that we discussed with Mr. Takemura on Monday?

A. I'm sorry, I need the page number you're talking about.

Q. Sure. It's the last three digits of the page is 376.

A. Yes, I'm there.

Q. And you'll see that there are Arabic numbers 1, 2, 3, 4. I'm referring to the first number, nature of the opinion.

A. Yes.

Q. And you were aware of this, correct?

A. Yes.

Q. Thank you. I'm not going to read it into the record, your Honor. If you'd like me to, I will, but this is the same information that was already read in the record.

THE COURT: It actually may be a good time to do it. It says, "Neither our opinion nor our report are to be construed as a fairness opinion as to the fairness of an actual or proposed transaction, the solvency opinion or investment recommendation but instead are the expression of our determination of the fair market value of the subject assets between a hypothetical willing buyer and a hypothetical willing seller in the assumed transaction on an assumed valuation date. For various reasons the price at which the subject assets might be sold in a specific transaction between specific parties on a specific date might be significantly different from the fair market value expressed in our report."

So I read that to refresh my own recollection and now you've heard it, too.

THE WITNESS: Thank you, your Honor.

MR. KORTMANSKY: Thank you, your Honor.

Q. So, Mr. Erb, you were aware that the KPMG report was not

intended as a fairness opinion as to the value of the transaction, correct?

A. Yes, the fairness opinion is a separate document.

Q. And you're also aware that this report was based on hypothetical buyer, hypothetical seller and a hypothetical, it's an actual transaction but a hypothetical buyer, a hypothetical seller, and in fact based on an assumed valuation date, correct?

A. That's what it says, yes.

Q. And you're also aware that the report says that the actual transaction may be very different.

A. They're referring to the subject assets, yes.

Q. I understand that, but you were referring to the subject assets, too, in your report, weren't you?

A. That's correct, yes.

Q. And it says that the actual transaction may be very different. You were aware of that as well, correct?

A. Yes.

Q. And yet you thought it was appropriate to rely on this report as the basis or the starting point for your opinion, correct?

A. Yes.

Q. Now, you understand that the KPMG report actually relied on what has been referred to as the confidential memorandum, it's Plaintiff's Exhibit 7?

A. No, I don't think it relied on that memorandum for more than -- let me back up a minute. The confidential memorandum was prepared by preacquisition management. After the assignment was given to KPMG to do the purchase price allocation they again consulted, as we saw in that e-mail exchange, with both Sekisui and its advisers -- excuse me, ADI and its advisers and Sekisui, and the numbers that they used as the basis for their long-term projections were provided by Mr. Hart in connection with consultations with Sekisui.

Q. Well, you recall testifying at a deposition, correct?

A. Yes.

Q. And when you did that you were being truthful at the time, correct?

A. Yes. Yes.

MR. KORTMANSKY: Your Honor, I'm going to read from Mr. Erb's deposition transcript. It's page 22 of Mr. Erb's deposition transcript. Do we have a copy for the judge?

THE COURT: I don't need it. Just in case your adversary wanted to follow it's page 22. Okay. Go ahead.

"Q. What did you do?

"A. We took the KPMG report as a starting point which in turn had used the confidential memorandum projections."

Do you recall testifying to that?

A. Yes. I think I just provided a more complete answer to that same question.

MR. WHITNEY: Your Honor, if he's going to keep reading from the transcript I would like him to provide me with a copy.

THE COURT: Don't you have the deposition of your own witness?

MR. WHITNEY: Not in front of me, your Honor. Now I have it.

THE COURT: You should have. It's elementary. You should have had it.

Q. Can we turn to what has been previously marked as Plaintiff's Exhibit 7? That's the confidential memorandum.

A. I need that exhibit. It's not in the binder.

THE COURT: Does he have the electronic disk that I have?

MR. KORTMANSKY: We'll provide a copy.

THE COURT: I don't need it, I have it electronically.

THE WITNESS: Here it is, I have it right now.

THE COURT: All right, he has it. I have it on the screen.

Q. Okay. Now, Mr. Erb, I'm just going to ask you to turn to what is Bates range number 979 which is also numbered page 5 in the document and the caption at the top is "confidentiality and disclaimer."

A. Yes.

Q. I want you to count down with me four paragraphs.

A. "The changes."

Q. "The changes involved," correct.

A. Yes.

MR. KORTMANSKY: And so I don't get accused of speaking way too fast from my colleagues, I'm going to ask your Honor if you could read in the sentence that starts, the second sentence, "This confidential memorandum also includes" and read it all the way through to the penultimate sentence.

THE COURT: Okay. "This confidential memorandum also includes certain statements, estimates, projections, including pro forma income statements and certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements, estimates, information and projections reflect significant assumptions and subjective judgments by the company's management concerning anticipated results. Such statements are subject to certain risks and uncertainties. The company cautions suitors not to place undue reliance on forward-looking statements which speak only as to management's expectations on the data herein. These assumptions and judgments may or may not prove to be correct and there can be no assurance that any projected results are obtained or will be realized."

Q. And you understood that at the time you prepared your report, correct?

A. Yes.

Q. And yet you relied on the information in this confidential memorandum because you also relied on the KPMG report which incorporated these particular objections?

A. Excuse me, the last sentence again?

Q. Which incorporated these projections.

A. Yes. And on the consultations by KPMG with the preacquisition management and Sekisui regarding these projections.

Q. We'll get to that in a moment, sir.

Could you please turn to the stock purchase agreement. PTX 3?

A. Yes.

THE COURT: It will be on the screen in no time, I'm sure.

MS. BRILEY: Do you have a copy, Mr. Erb?

THE WITNESS: Yes.

THE COURT: What Bates page would you like me to go to?

MR. KORTMANSKY: I'm getting there, your Honor. It's Section 4.29, which is page 41 of the stock purchase agreement and its last two digits of the Bates range is 88.

THE COURT: 88?

MR. KORTMANSKY: 88, in my copy. Oh, I'm in DX A. It's still page 41.

THE COURT: And it is 88. All right, which paragraph

number?

MR. KORTMANSKY: It's 4.29 and again if your Honor could read it.

THE COURT: Okay. It's called disclaimer of other representations and warranties. It says, "Except as otherwise expressly set forth in this Article IV including the schedules attached hereto, neither the principal shareholders nor the company makes any representation or warranty, express or implied, at law or in equity in respect of the company or any of its assets, liabilities or operations. The representations and warranties set forth in this Article IV supersede and replace all prior statements, representations, projections, forecasts, warranties and other understandings whether written or oral that may have been previously given or made by the principal shareholders and the company that may have related in any way to the subject matter of this agreement, including the projections set forth in the confidential memorandum relating to the company dated August 2008/October 22, 2008."

Q. And you understood that as well when you prepared your report, didn't you, Mr. Erb?

A. Yes.

Q. And it's your understanding that what's been previously marked as Plaintiff's Exhibit 8 somehow exonerated those provisions, is that right?

THE COURT: I'm sorry, what is 8?

MR. KORTMANSKY: I'm sorry, Plaintiff's Exhibit 8 is the e-mail exchange that was referred to earlier today.

A. I wouldn't use that term, but the KPMG assignment was to allocate the purchase price among the various assets of the company and in so doing or in preparation to do that they consulted with ADI, which at that time was the same as preacquisition management and with Sekisui and with the advisers of the buyer and the seller and at that time it was deemed by that group appropriate to use the projections that the PPA contained.

THE COURT: I'm sorry, I just couldn't catch that whole answer. I'm going to have to read it back.

(Pause)

THE COURT: Exhibit 8 was written in June '09? The e-mail exchange was June of 2009, right?

THE WITNESS: That's correct, right.

THE COURT: And the closing again was?

MR. WHITNEY: April 2009.

THE COURT: April 2009. So these are post-closing statements. So, Mr. Kortmansky, I'm confused by your question because the article we just read of the stock purchase agreement talks about any statements made up to that time. They're all superseded by the terms of the stock purchase agreement. This is the statement that postdates the closing, right?

MR. KORTMANSKY: Let me address that, your Honor.

THE COURT: Okay.

Q. So, let's turn to what is page 2 of the e-mail.

THE COURT: E-mail, okay.

THE WITNESS: This is PTX 8?

Q. Yes, PTX 8.

A. I have it.

Q. It says --

MR. KORTMANSKY: Actually, your Honor, again, if you could, I'll read aloud and do my best to be slow.

THE COURT: The one that says, "Hi Jeff and Doron?"

MR. KORTMANSKY: "Hi Jeff and Doron."

THE COURT: "We are currently working on a purchase price allocation assignment for Sekisui and as part of that we would like to understand in some more detail the basis for ADI projection numbers in the offering memorandum. We understand CrossTree helped ADI put that together. If it is okay, Takesumi Semba from our valuation practice would like to talk to you. Let me know if he can do that."

Q. And what happens next is that Mr. Ellis responds, and he says, in sum, sure, we would be happy to talk to you, isn't that what that says?

A. Yes.

Q. Then what happens is actually there is a communication with questions, right, that's what happens? That's the next e-mail

on page 1?

A. Yes.

Q. And Mr. Ellis simply responds to those questions, correct?

A. Yes.

Q. So this wasn't somehow a communication that was intended to suddenly make the statements and the projections in the confidential memorandum new warranties or a reaffirmation of the information in the confidential memorandum, was it?

A. No.

Q. Thank you. And as we already discussed the KPMG report was not used to value the purchase when they actually bought it, right?

A. That was established in the stock purchase agreement.

Q. If we can just go back one more time to Plaintiff's Exhibit 7, the confidentiality memorandum, and turn again to the same page 5. And we're going to read from one paragraph further down than the last paragraph. This one starts, "Except where otherwise indicated."

THE COURT: Okay. "Except where otherwise indicated, this confidential memorandum speaks as of the date of August 2008. Neither the delivery of this confidential memorandum for the investment in the company shall under any circumstances create any implication that there has been no change in the affairs of the company since the date hereof. In furnishing this confidential memorandum neither the company nor

CrossTree undertakes any obligation to update any of the information contained herein."

Q. Now, Mr. Erb, you were also aware of that paragraph?

A. Yes.

Q. And as a reminder the closing date was in April of 2009, correct?

A. Yes.

Q. And so this confidential memorandum and whatever information is in it relates to projections from seven months earlier? The math might be wrong. I'm not a mathematician. Six or seven months early earlier, is that correct?

A. Yes.

Q. And there's no requirement by the company to update the information here, correct?

A. As of this date, yes.

Q. Or any date, there's no obligation to update.

A. Yes, that's correct.

Q. And there's no representation here that the company could completely change -- strike that. There's no representation here that the company will not change substantially before the closing date, correct?

A. Yes.

Q. Yet you still believed that the projections in this document were appropriate to rely on for an April 20, 2009 valuation date?

A. Well, this goes back to the point we were just discussing in PTX 8. Because of the factors that you've alluded to here I believe that was probably one of the reasons why KPMG undertook to consult with the company, its preacquisition management, which was still in place, and with Sekisui saying here are the projections in the confidential memorandum, can you explain them, and at that time if there had been any hesitation or reservation on the part of either party about using these projections I'm sure they would have said so.

MR. KORTMANSKY: I move to strike that, your Honor.

THE COURT: Well, that was responsive.

Q. You don't actually know what happened in those conversations, do you?

A. No. No.

Q. And the only evidence in the record is that there were some requests made by Sekisui and KPMG to ask management or, as you say, preclosing management, to explain some of the projections that were in the confidential memorandum, right?

A. That is in the record but we also have the statements in the PPA itself about their consultations. We don't know that this was the only consultation.

Q. But there's no indication that these confidential memorandum projected were rewarranted or reaffirmed?

A. No.

MR. KORTMANSKY: Give me one moment, your Honor, just

to make it easy. This is that giant spreadsheet that we looked at on Monday. Thank you.

Q. Mr. Erb, you were here on Monday when Mr. Takemura was testifying regarding the spreadsheet that is now up on the screen.

A. Yes.

Q. And do you recall his testimony that the appropriateness of the acquisition and the purchase price, which is 25 and a half million dollars was based on the third red and green bar? I can point you to the transcript reference if you need but you probably remember that testimony, don't you?

A. In general terms, yes. However if we're going to discuss specific parts of these charts I think it would be good to review the testimony.

Q. We can review if you'd like. I'll get the transcript reference for you, Mr. Erb.

THE COURT: Your Honor, I'm assuming that all copies of the transcript are the same. It's a draft transcript, page numbers may vary, but in my version of the transcript, you actually asked Mr. Takemura on page 120, line 25, "Look at page 2, that little box, do you see on page 2 it says the above analysis we conclude the acquisition price to be appropriate? When you gave that testimony, what above analysis were you referring to?

"A. That's correct. It's particularly referring to the bottom

bar graph."

"The bottom bar graph," the Court asks. Court: "Show me which bar graph you're pointing to. Can you show me on the paper which bar graph is he pointing to? Okay."

And now your Honor is still speaking. "He pointed to the third red and green bar."

"Q. And we've established have we not, Mr. Takemura, that the acquisition price you're talking about is 25 and a half million dollars, is that correct?

"A. Yes."

Do you recall that testimony?

A. Yes, I do.

Q. And do you recall that that third bar graph is an analysis of the appropriateness of the acquisition price without Femtelle?

MR. WHITNEY: Object to the extent that misstates the prior testimony. I don't have the portions of the transcript that he's reading from.

MR. KORTMANSKY: I can read it, your Honor, if you like. If the witness doesn't recall I can read it to him.

THE WITNESS: I don't recall so we'll have to go back to the transcript. Thank you.

Q. This is question from Mr. Velie. "So your -- let's go back to page 2, the first page we were using. So the final bar graph, the last one is also sensitivity analysis, only core

plus synergy. Sensitivity analysis only core. So three and four are again no Femtelle, is that correct?

"A. Yes."

Does that refresh your recollection, Mr. Erb?

THE WITNESS: Yes.

THE COURT: I do forget what the red and the green are, however.

MR. KORTMANSKY: I believe the red is without sensitive -- excuse me, the red is without synergy and the green includes it, your Honor.

MR. WHITNEY: Green is synergy.

THE COURT: Oh, right, it says green synergy. I see that little box to the right.

Q. And, Mr. Erb, do you also recall Mr. Takemura testifying that Sekisui would only pay for Femtelle if it made some money? Do you recall that testimony?

A. No.

Q. All right. Well, let's go back to the transcript.

MR. KORTMANSKY: Your Honor, I'm now reading from page 124. This is line 7 through 12.

THE COURT: This is still Mr. Takemura?

MR. KORTMANSKY: This is still Mr. Takemura. It's in response to -- there was a very long back and forth but I'm just going to read the answer, question and answer. This is now Mr. Takemura's answer. "Yes at the very top portion we're

only assessing the core. The overall evaluation is certainly inclusive of Femtelle.

"Q. And then you'll pay for Femtelle later if it makes some money, is that right?

"A. Yes. If it went beyond a certain level."

Q. Do you recall that testimony?

A. Yes.

Q. Now, despite that testimony, despite Sekisui specifically evaluating the purchase price without Femtelle and despite Mr. Takemura specifically saying that they'll only pay for Femtelle later --

A. That is not my understanding of what he said.

Q. No?

THE COURT: Nor mine, but you're welcome to read that again. That's not what I thought I just heard.

"Q. And then you'll pay for Femtelle later if it makes some money, is that right?

"A. Yes, if it went beyond a certain level."

THE COURT: Yes. If it went beyond a certain level.

MR. KORTMANSKY: So it's not even a guaranteed payment.

THE COURT: That's not the way I'm hearing that. I don't know if Mr. Erb is hearing the same way I am. It seems to say if it goes beyond a certain level more money, but up to that level it's included. That's what I thought -- the first

part I thought he said inclusive of Femtelle. Would you read that again?

MR. KORTMANSKY: It says the very top portion which is the acquisition price above it, we're only evaluating -- where is it, we're only assessing the core, so the acquisition price --

THE COURT: No, you read the whole thing. It had the word "inclusive." Read it.

MR. KORTMANSKY: It says, for the overall evaluation it's certainly inclusive of Femtelle. We don't dispute that, your Honor. For the overall evaluation they're doing for the acquisition rather than the acquisition prep, how much they're going to pay. And then he says, "and then you'll pay for Femtelle later if it makes some money, is that right?" He answered, "Yes, because the acquisition price" --

THE COURT: No, no, yes, only if --

MR. KORTMANSKY: Only if it went beyond a certain level.

MR. WHITNEY: I object to defendant's characterization of Mr. Takemura's testimony. Mr. Kortmansky --

THE COURT: We're going to get to that in summation anyway. You can object to it now but he's going to do exactly that this afternoon.

MR. WHITNEY: He keeps saying only pay for Femtelle. That's not what Mr. Takemura said.

MR. KORTMANSKY: Fair enough. Thank you Mr. Whitney.

Q. Now, Mr. Erb did you consider in preparing your analysis Sekisui's analysis of the acquisition price?

A. Yes.

Q. Well, where in your report do you describe that the acquisition price of 25 and a half million dollars is appropriate without Femtelle?

A. I don't believe that's a fair reading of the document. Mr. Takemura also testified that the deal wouldn't have been done without Femtelle because it needed Femtelle to get to an established benchmark used by the authorities of the company or its subsidiaries to determine -- my recollection is there was an 11 percent return required and he said that you needed in another part of this analysis Femtelle in there to get to that benchmark. I would also comment on the previous exchange that my interpretation of that paragraph is he's referring to the earnout payments.

MR. KORTMANSKY: Thank you. That's exactly right.

THE COURT: Can you pause for a minute? I just wanted to read that last answer.

(Pause)

THE COURT: Okay. Thank you. I'm ready if you are.

MR. KORTMANSKY: We're getting another -- I'm sorry, it's our exhibit, DX MM. This is the Savvian report from February 6, 2009, your Honor.

THE COURT: All I want to know is has it been handed to us? Do we already have it?

MS. BRILEY: It has been introduced. I can hand you another copy.

THE COURT: I might have it. It's called MM?

MS. BRILEY: That's correct.

THE COURT: I don't know if I kept it. Let me look through my pile.

THE WITNESS: Let me show you the cover, your Honor.

MS. BRILEY: I'm happy to provide you another copy.

THE COURT: It's up to you. There's a lot of paper around.

MS. BRILEY: We can always take it back later.

THE COURT: Okay. What is this again?

MR. KORTMANSKY: This is the report prepared by GCH Savvian.

THE COURT: Yes.

Q. Mr. Erb, you understood Savvian to be Sekisui's investment banking advisor for the transaction, correct?

A. I do.

Q. And you've seen this report before, correct?

A. Yes. I'm having trouble. It seems to be paginated --

Q. I'm sorry, the report was issued in Japanese. There's an English translation behind it also attached.

A. Actually it's sort of inter collated with my version here.

THE COURT: No, at some point --

THE WITNESS: Here. This is the cover page?

THE COURT: There's a page 1 dated February 6, 2009. Do you see that? Are we looking at the same cover page?

THE WITNESS: Yes.

THE COURT: Okay, we're on the same page. Okay. Okay. Anyway, we're both here, February 6, 2009.

MR. KORTMANSKY: Thank you, your Honor.

Q. I'm not going to ask this to be read back in the record because it's already been read once. My question to you, Mr. Erb, do you recall Mr. Takemura's testimony that in preparing his presentation to the board of Sekisui or to management of Sekisui for approval he did not rely on what was in the Savvian report?

A. Yes.

Q. Do you recall that?

A. I do.

Q. And that, the meeting where he first discusses it, there's a February 9 management meeting for approval, do you remember that?

A. I don't recall that date, no.

Q. Your Honor, we'll keep going back, February 9 --

THE COURT: You repeated that. I'll accept there was a meeting on February 9. But he testified he did not rely?

MR. KORTMANSKY: Did not rely. That's his testimony.

I don't hear Mr. Whitney objecting so I must not be stating something which is not accurate.

Q. Now, the date of Plaintiff's Exhibit 49 is March 27.

THE COURT: Wait, I'm lost.

MR. KORTMANSKY: The big spreadsheet, Plaintiff's Exhibit 49.

THE COURT: That's March what?

MR. KORTMANSKY: March 27.

THE COURT: March 27, okay.

THE WITNESS: Excuse me. I believe Mr. Takemura testified there were several versions of this and there were earlier considerations and the document essentially remained unchanged as it went through various meetings including meetings with, as I recall, the English-speaking team in the United States.

Q. I understand that, Mr. Erb. I'm talking about now this February 6, 2009 document issued three days before that meeting, the February 9 management meeting.

MR. KORTMANSKY: And I'll represent this to the Court and for the record that we received no other valuations after this February 6, 2009 valuation from Sekisui. So if it existed it was not produced to us.

A. Yes.

Q. And this date, March 27, 2009, Mr. Takemura explained was because he had to meet with some additional members of

management who had not attended the first meeting.

A. I recall that.

Q. Now, you're a very experienced investment banker. Do you believe that an officer of a company who is asking management of the company to spend millions and millions of dollars to purchase an asset and to purchase an asset that's going to have this contingent component of Femtelle, in fact it's a very difficult asset to value, and he's going to present to management not once but twice a month and a half apart without relying on the report prepared by the investment banker they hired to evaluate the transaction? In your experience, is that something that gets done?

MR. WHITNEY: Objection. This is not expert opinion what Mr. Takemura intended to do and why he did it.

THE COURT: I do understand that, but given Mr. Erb's qualifications and given his reliance on various evaluations, all the question is asking, it was very long winded but it was asking essentially isn't it odd that he didn't bring to the attention of his board or his managers the evaluation prepared by his own investment banker.

A. I don't find it odd, because I -- we have to look at this particular document. To answer the general question, of course there are lots of factors that go into an evaluation what a banker said and I can't tell you what a board or individual should do, but in this particular case I find there is an

inaccurate expression of what was at stake in this transaction and I can explain that by going to Exhibit A to the SPA or that's the document that I think explains the situation. But on pages 6 and 7 in this document there are what I regard as inadequate or partial explanations of what's going on in the transaction, so if I had been an executive looking at this report I would have said, oh, there's something missing from this table and I will rely on other factors as well as whatever I'm receiving from the investment bank.

Q. And Exhibit A is the future payments that would have to be made for Femtelle, is that correct?

A. That's a schedule of future payment, yes.

MR. WHITNEY: Your Honor, he's referring to Exhibit A to the SPA.

THE WITNESS: Yes. Did I misspeak?

THE COURT: No, you said that, Exhibit A to the SPA.

Q. Mr. Erb, in your report you testified earlier you assigned damages both for the cost of -- sorry, both for the estimated cost of remediation -- do you remember testifying about that this morning, $1.4 million?

A. I did.

Q. The estimated cost for remediation.

A. Yes.

Q. And then you also charged the Harts for the actual cost of remediation. Don't you do that?

A. No.
Q. What makes you think that you have not done that?
A. The damages --
Q. Strike that. That's a bad question. Please explain why it is that you believe that you have not done that.
A. The damages calculations were as I described, your Honor, and the remediation costs in the damages estimate were the present value of damage estimates which I made. Subsequent to the preparation of my first report I learned that there had been new information regarding one of the aspects, one of the issues that I included in my firs estimate of the costs incurred and so I reproduced the costs incurred without that change. That claim was no longer asserted and I felt obliged to correct the record, but I did not rely on the section of my report, supplemental report concerning costs incurred in the calculation of my damages.
Q. I'm not sure that answered my question.
THE COURT: All he's asking you, did you double count remediation expenses?
THE WITNESS: No.
THE COURT: Is it in there once, the 1.4 million is the only time the remediation expense is there?
THE WITNESS: Yes.
THE COURT: It's not in the other parts of the total, the Femtelle was overvalued and the current assets were

overvalued?

MR. KORTMANSKY: And there was no testimony regarding it this morning, so maybe Mr. Erb is now eliminating from his report the actual expenses, the out-of-pocket expenses Sekisui claims to have incurred for --

THE COURT: As opposed to remediation expenses?

MR. KORTMANSKY: Let me try --

THE COURT: Separate and apart from remediation there was something called out-of-pocket?

MR. KORTMANSKY: They actually prepared in their report a $2.9 million claim the actual cost of remediation they incurred.

THE COURT: I think now it's 1.4 million.

THE WITNESS: That's right.

THE COURT: And prejudgment interest and attorneys fees. That's it.

MR. WHITNEY: Your Honor, this wasn't in the record. He's not testifying to that.

THE COURT: The only remediation costs sought is 1.4 million, not 2.9. The other two components of the total damage -- do you want to see that slide? The two components was the overvaluing of the Femtelle and overvaluing of the other assets, that's it, and 1.4 for remediation?

THE WITNESS: Yes.

MR. KORTMANSKY: May I have a moment?

THE COURT: Sure.

MR. KORTMANSKY: Your Honor, can we just ask Mr. Whitney to put up the slide of the calculation of damages by Mr. Erb?

THE COURT: Sure.

MR. WHITNEY: I believe the last slide.

MR. KORTMANSKY: Just one more moment, your Honor.

(Pause)

Q. Mr. Erb, this is the total damages Sekisui is asking for in this litigation, is that correct?

THE COURT: No, plus prejudgment interest and attorneys fees.

MR. KORTMANSKY: Correct, your Honor.

A. These are my calculations of the total damages.

THE COURT: Well, then, we can find out from counsel. Is counsel seeking anything that this witness is not mentioning?

MR. WHITNEY: No, your Honor, other than prejudgment interest and attorneys fees.

THE COURT: I said that three times. So not only is it -- I just want to make sure you heard that. Not only Mr. Erb is saying this but so is the plaintiff. This is what they're seeking.

Q. So, Mr. Erb -- and thank you for clarification, Mr. Whitney. Mr. Erb, in your report you included damages for

a lease, you included damages for lyophilization, Mr. Whitney is that all out now?

MR. WHITNEY: Your Honor, I object to this testimony, he did not testify to any of this information. It's not in the record.

THE COURT: But he said it's in the report. Apparently it's not being sought any longer. This is it. Mr. Whitney just confirmed, this chart is it. This chart is it.

MR. KORTMANSKY: Your Honor, the discussion going on, and perhaps if you actually can give us a couple of minutes without interrupting you back and forth is to determine whether we're actually done or we need something more.

THE COURT: Okay.

MR. KORTMANSKY: And so if it's okay with you, if we can take a three-minute recess and discuss with Mr. Velie we could be through with this witness.

THE COURT: Okay. It would be good to know before the lunch recess, it will be good to know if you're done. So we'll sit here while you confer for three minutes. You can confer outside the room, too. You can go use the jury room.

MR. KORTMANSKY: Thank you, we'll do that.

MR. VELIE: Thank you, your Honor.

(Recess)

MR. KORTMANSKY: Your Honor, I have no further questions for this witness.

THE COURT: Okay, good. Redirect?

REDIRECT EXAMINATION

BY MR. WHITNEY:

Q. Mr. Erb, could you take a look at PTX 48, please? I know we've seen this document already.

A. Yes.

Q. And counsel, defense counsel has referred you to a statement on page 2 regarding the intended use of this document, do you see that?

A. Page 2 of the letter?

Q. Page 2 of the letter. Page 2 of the document, page 1 of the letter, the first paragraph which we've seen and read many times. It doesn't say here that any other use of this information is precluded, does it, Mr. Erb?

A. No, it does not.

Q. And why did you rely on this?

A. Well, it was, as I stated earlier, I thought it an unbiased third party report which had been very carefully prepared using information from the company on the company, company information from preacquisition management and there were consultations with both the companies, the buyer and seller, and their advisers and it estimated, the allocation included the estimated fair values of the components of the transaction and that was really an excellent basis I thought for proceeding with analysis of the issues that we looked at.

Q. And those values were bounded by the purchase price agreed to by the party, correct?
A. That's correct. And we did not take, go outside that limit, that's right.
Q. If we could look at PTX 7. Bates number ending in 979.
A. Yes.
Q. In the, I believe the fourth paragraph there was some reading of the language in the agreement, in the memorandum. Do you recall that?
A. I do.
Q. Have you ever seen that type of language before in any financial projections, Mr. Erb?
A. Yes. It's normally in any information memorandum or confidential memorandum. It's done to conform with the securities laws.
Q. Is this standard boilerplate language you've seen in almost any projections you've looked at?
A. Standard language, yes. Not necessarily exactly the same but yes, standard language.
Q. Let's go to Exhibit 3. Do you recall reading Section 4.29 of the SPA?
A. I do, but I'd like to see it. Yes.
Q. You're not relying on the projections in the confidential memorandum for a determination that the failure to meet any of the projections is a breach of this agreement, are you?

A. No.
Q. What are you relying on the projections for, if at all?
A. Well, they were, these projections formed an input into the PPA analysis. That's how I used them. I didn't use this document, per se, but the inclusion of consistent projections which had been accepted by KPMG after consulting with preacquisition management and advisers and Sekisui, as I stated before.
Q. KPMG consulted with the preparer of the confidential memorandum before using the information, correct?
A. That's right. We saw that in the e-mail involving Mr. Semba.
Q. Have you seen any information in the record, any evidence in the record stating that anyone from CrossTree or ADI or Mr. Hart said not to use those projections?
A. No, I have not.
Q. Did you see any evidence in the record to the contrary?
A. No.
Q. Did you hear the testimony of Mr. Takemura?
A. I did.
Q. Do you recall that Mr. Takemura confirmed that Mr. Hart actually provided the Femtelle projections to KPMG?
A. I did.
Q. And in your analysis were those projections actually the same projections that were used in the confidential memorandum?

A. Yes. Regarding Femtelle.

Q. Regarding Femtelle, correct.

You mentioned earlier that you could explain -- withdraw that. Is it your opinion that the only payment for Femtelle in the SPA is contained in the earnout as defendants are contending?

A. No.

Q. Will you look at I think what's PTX 5 which is Exhibit A to the SPA?

A. Yes.

Q. Does this help inform your opinion?

A. Yes, it does.

Q. How does it do that?

A. This is a schedule of payments that would be made under the terms of the SPA if sales, that is revenue, from Femtelle reached certain levels. But you see, your Honor, at the bottom of the table the earnout commences if sales reach $2,526,000. But sales below that number, if one dollar less, one dollar was subtracted from each of these numbers all that revenue would still take place and would generate earnings for the company and it adds up to roughly $20 million, your Honor.

THE COURT: 20 million from when to when?

THE WITNESS: From 2010 to 2013. That is to say, if you add up 25, 125, 46, 999, that adds up to roughly, 20, $21 million and that is real value that pertains to sales of

Femtelle under the assumptions that, under the assumptions that had been made in the PPA. And this is the document, as I said, this is part of the purchase agreement which says that earnout pages will be paid only between 2526 in the first year and 4042, the scale goes up by $500,000 a year, and this is also embodied in that value analysis that we discussed, there's a chart in there --

THE COURT: No, not 500,000 a year?

THE WITNESS: I'm saying that the top line, your Honor, it goes from --

THE COURT: Oh, during the --

THE WITNESS: If you look at the payment column.

THE COURT: I am.

THE WITNESS: The first year you're going to go from 1 million to 1.5.

THE COURT: Oh, the payment column. Okay.

THE WITNESS: If it exceeds that number you're still capped at 1.5. The next year it's 2 million, next year 2,000,500. That's what I'm saying. So there's a bound at the bottom and the top and below the trigger level which is 2526 the revenue goes to the company, Sekisui, and no payments are made to the sellers.

I would also say that I find it unreasonable to say that they wanted nothing from Femtelle when we have evidence that Richard Hart wanted consideration for the sums that had

been invested prior to this transaction.
Q. Under the structure of the earnout payments, Sekisui can make tens of millions of dollars of revenue from Femtelle and not be paid a penny of the, earnout is that correct?
A. That's right. And that was the heart of my objection to the Savvian document we reviewed because it left that out.
Q. And in addition at the top end of the earnout Sekisui could make tens of millions, infinitely more money, and not pay a penny more for an earnout, is that correct?
A. Yes.
Q. So in your expert opinion having valued some amount of M and A transactions and purchase agreements, do you believe that the value of Femtelle is solely contained within the earnout payments?
A. No, I do not.
MR. WHITNEY: Thank you, your Honor.
MR. KORTMANSKY: I have no questions, your Honor.
THE COURT: Thank you. You're done.
THE WITNESS: Thank you.
(Witness excused)
THE COURT: All right. Are there new exhibits?
MR. WHITNEY: Your Honor, can we have the lunch break -- oh, for Mr. Erb?
THE COURT: Yes.
MR. WHITNEY: I believe all the exhibits I used on

redirect were already --

THE COURT: Not redirect.

MR. WHITNEY: I read all the exhibits I used before.

THE COURT: Subject to checking your exhibit list does the plaintiff rest?

MR. WHITNEY: Could we have the lunch break just to make a determination? We have no more witnesses.

THE COURT: That's what I said, subject to your adding to your exhibits or going over your exhibit list does the plaintiff rest?

MR. WHITNEY: Yes.

MS. HAGBERG: We just have one question that we wanted to raise with the Court about the spoliation and rebutting the presumption and how you wanted to handle that because some of the exhibits we would have used would have been -- we weren't sure whether you wanted us to do that during the trial itself or you wanted us to do that in briefing afterwards.

THE COURT: I would have thought during the trial itself.

MS. HAGBERG: We have --

THE COURT: I was going to say and I remember you did a couple --

MS. HAGBERG: We have, your Honor, but because it's not clear to us exactly what presumptions they are seeking, it's difficult --

THE COURT: That the material that's missing would have been favorable to the defense.

MS. HAGBERG: I'm going to ask, Mr. Whitney had prepared to --

MR. WHITNEY: Sorry, your Honor. I thought I would address this after lunch. So Mr. Velie asked in his opening I think five different adverse inferences. As your Honor states these are permissive inferences not mandatory inferences and to the extent that your Honor chooses to take those adverse inferences we have the right to rebut those inferences.

THE COURT: Correct.

MR. WHITNEY: We believe that none of those inferences should be taken, but in the event that the Court decides to take those adverse inferences we'd like the ability to put into the record exhibits we believe --

THE COURT: You have to do that now. We're not reconvening this trial. I'm not going to issue a ruling on this whole trial and have it be a tentative ruling subject to rebuttal. No, we do it now. One record, close the record, rule and be done, then there's another Court, but that's it.

MR. WHITNEY: Sorry if I wasn't clear. When we reconvene from lunch we'll move in any exhibits we have to rebut that presumption.

MR. VELIE: One housekeeping. Is your practice with respect to summations to have defendant first then plaintiff or

do you want plaintiff-defendant-plaintiff?

THE COURT: I never do three in civil cases. That's out. There's one each. As to who goes first, it would be the party with the burden of proof goes last. The problem is that there's a counterclaim here, so to some extent you both have the burden of proof but on the openings who did I hear from first?

MS. HAGBERG: You heard from me first, your Honor.

THE COURT: Then Mr. Velie can go last. So it will be plaintiff first and then defendant. That's it.

MS. HAGBERG: Your Honor, would it be possible to take a slightly longer lunch break to prepare?

THE COURT: I want to make sure Mr. Velie has not changed his mind from last night. Is it still your decision to call no witnesses?

MR. VELIE: Yes, your Honor. That's our decision.

THE COURT: Okay.

MR. VELIE: I will explain it in summation if that would be helpful to the Court.

THE COURT: That's fine. As I said yesterday it's completely your call. Okay.

MS. BRILEY: And, your Honor, we do need to, we did not move our exhibits from yesterday and this morning into evidence yet so at some point we will need to do that. Now is fine or after lunch?

THE COURT: Now is fine. Let's get the record going so when we get back from lunch, extended lunch break, we can get into summation.

MR. VELIE: One final point, your Honor. Do you want to hear, when they close, when they say they're done with their case do you want to hear motions then or do you just want to decide the case?

THE COURT: I think you have to preserve your motions, but I sincerely doubt this is a case where any of the claims are going to be disposed of on motion. What I would usually do in a non-jury trial after all this is reserve decision on the motions, close the case, rule and if I grant it on motion as opposed to decisions it's quite a trivial difference. You need to preserve them so you need to very briefly state your positions as does plaintiff if they want to move on their counterclaim. That's all brief. I'll take that on summation.

You were going to read the list of exhibits first then we'll reconvene at 2:30.

MS. BRILEY: DX C, DX E, DX 8Q, DX 8A, DX 8R, DX 8C, DX 8S, DX 8D, DX 8U, DX 8I is, DX 8J. Thank you.

THE COURT: All right, 2:30. See you then.

(Defendant's Exhibits C, E, 8Q, 8A, 8R, 8C, 8S, 8D, 8U, 8I, 8J received in evidence)

(Luncheon recess)

(Continued next page)

A F T E R N O O N S E S S I O N

2:30 P.M.

THE DEPUTY CLERK: All rise.

THE COURT: All right, please be seated.

All right, Ms. Hagberg, are you going to --

MS. HAGBERG: I think, your Honor, before we close, we were going to make put in our exhibits, and we'll be quick.

THE COURT: All right.

MR. WHITNEY: I got to get Ms. Fleming. She has the --

MS. BRILEY: Your Honor, we also would like to enter some exhibits. I could just go ahead with that.

MR. WHITNEY: Start with the defendant.

MS. BRILEY: DX-3Z, DX-2I, DX-5G, DX-4O, DX-4Q.

THE COURT: What are all of those? Those were not shown to any witness?

MS. BRILEY: That's correct, these are on our exhibit list and they were not shown to a witness, nor objected to.

THE COURT: That's good, but why are they being put in?

MR. VELIE: We could do it after they rest if you like. It would be our case.

THE COURT: Say again?

MS. BRILEY: We could wait to explain the basis for these exhibits after they've put in their exhibits and rested

and --

THE COURT: That's fine. All right. You ready to read your list?

MR. WHITNEY: Yes. The PTX-1, PTX-15, PTX-44, PTX-103, PTX-130.

THE COURT: Let me interrupt. Are all of these not shown to any witness.

MR. WHITNEY: No, your Honor. They're just, they're admissions and they're just statements or facts for the record.

THE COURT: I don't know what that means. This is an unusual procedure. I've been doing this a long time. I don't know what these free floating exhibits are that aren't being shown to witnesses. What are these? You said admissions. Some of these statements of --

MR. WHITNEY: Statements of the party opponent. We would have offered them through the defendant's case in chief, they didn't put one on, so we're just going to offer them into the record in our case in chief.

THE COURT: You said that some of them.

MR. WHITNEY: Well, they're some business records.

THE COURT: Business records of who? I mean I can't --

MR. WHITNEY: So --

THE COURT: I'm sorry, I'm not about to do the work for you. If I don't know why an exhibit's in evidence, I can't

deal with it.

MR. WHITNEY: Sure.

THE COURT: Whose business records? How do I know it's a business record. You are saying here's 20 things, you solve the problem. So I'm not accepting -- I'll accept the ones that you're calling admissions and only those. Which are those? Those are not in evidence. Sorry.

MR. WHITNEY: PTX-15. And then, your Honor, we have the documents that we were going to use to rebut the adverse inference. So that's a separate set that I want to present.

THE COURT: Separate set.

MR. WHITNEY: Yes.

THE COURT: Not some of the ones you started to read?

MR. WHITNEY: No. I'll give you the separate set.

THE COURT: All right.

MR. WHITNEY: Let me confer with my colleague.

So this is PTX-281 and PTX-282. I'll hand you copies because they're rebuttal exhibits so they weren't on our original list

MS. BRILEY: Your Honor, we object to PTX-282. This document was created after the relevant time period after the company was sold to plaintiffs.

THE COURT: Yes, but that's not the point. That would be exactly the appropriate time period, I think. Your point is certain information was deleted or destroyed, whatever the

right word is, in 2000 -- I don't know what 11, 12 or 13. So of course this policy was in effect then, that is the appropriate time period.

MS. BRILEY: That was our point. Thank you.

THE COURT: So anyway I'm receiving 281 and 282 in evidence.

(Plaintiff's Exhibits 281 and 282 received in evidence)

MR. WHITNEY: Then 279 and 280, which are both admissions.

THE COURT: One second. Just one second, please. I'm sorry, what's next?

MR. WHITNEY: 279 and 280.

THE COURT: The same issue? Is this on the same issue?

MR. WHITNEY: These are admissions, your Honor.

THE COURT: Oh, there's admissions?

MR. WHITNEY: Yes.

THE COURT: These are statements of ADI?

MR. WHITNEY: These are statements of the Harts.

THE COURT: Harts.

MR. VELIE: Your Honor, we object to these because they were not on the exhibit list.

THE COURT: Right. But he's saying he expected there to be a defense case, he was going to use them for rebuttal.

There is no way he could.

MR. VELIE: He was going to use them for impeachment, presumably.

THE COURT: Fine. Impeachment or rebuttal. Either way, he didn't expect there to be no defense case. Frankly, neither did I. You listed a group of witnesses, you said your case would take two days. We don't play games. He was going to use these exhibits. He was not required to offer them in his case in chief. Now you rested now, he wants to put in, hopefully not too very am, looks like right now there is two of them, 279 and 280. One is an e-mail from Mr. Hart dated June 23rd, 2010 and one is Mrs. Hart April 12th, 2012.

MS. BRILEY: Your Honor, we do object to PTX-280. Mrs. Hart testified at deposition that she did not write this e-mail. We have --

THE COURT: That's nice, that's not in the trial record. I can't take what she said in deposition. You're welcome to call her.

MS. BRILEY: They're adding it to the trial.

THE COURT: I know. So you're welcome to call her. I don't deal with deposition testimony. I deal with what occurs in my courtroom. You can call her. You can call Mr. Besze, you can call any witness you want. You gave me a whole list of witnesses. You want to take, her take the stand for one minute, say she didn't write this, that's fine, but then she's

open to cross-examination on that issue, but it's up to you.

MS. BRILEY: Just on that issue.

THE COURT: Yeah, take one second. She doesn't even have to walk up. Just raise your right hand.

LOUISE HART,

called as a witness by the defendant,

having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MS. BRILEY:

THE COURT: Fine. Take a look at Exhibit 280. It purports to be an e-mail from you to you dated April 12th, 2012. It's titled "thoughts on Vince." Would you read this to yourself and then tell me whether you wrote this e-mail?

THE WITNESS: I did not write this e-mail.

THE COURT: All right. Have you ever seen it before?

THE WITNESS: I was shown this e-mail during my deposition.

THE COURT: And that was the first time you saw it?

THE WITNESS: That's correct.

THE COURT: All right, thank you.

Any questions for the witness on this subject only?

CROSS EXAMINATION

BY MR. WHITNEY:

Q. Is this your e-mail address, Mrs. Hart?

A. I don't have the paper in front of me. Yes, it is.

Q. Okay. And does the designation show that it came from your files, the Hart Bates stamp?

A. Well, it's from Louise Hart to Louise Hart, but I didn't write that e-mail.

THE COURT: He means the Bates stamp in the lower right-hand corner, hart and a bunch of numbers. Does that indicate to you that it came from the files?

THE WITNESS: I have no clue.

THE COURT: You don't know, okay.

MS. BRILEY: We'll represent that it does.

THE COURT: All right.

Q. And is Callback@hotmail.com the e-mail address that you normally use.

A. I do.

Q. And does anyone else normally use that e-mail address?

A. No.

MR. WHITNEY: Your Honor, I think it's pretty clear that this came from Mrs. Hart. Who else --

THE COURT: She denies it, so that's --

MS. BRILEY: One further question.

REDIRECT EXAMINATION

BY MS. BRILEY:

Q. Does anyone else have access to your e-mail address?

A. No. Sometimes my son, who is right there, uses my hot mail account. And I believe he was the one who wrote that.

THE COURT: Oh, maybe.

Q. But you don't know?

A. I don't know.

Q. Okay, thank you.

THE COURT: Okay, all right. I'll take it in evidence, but I may choose not to give it any weight in view of the testimony, but it's in evidence. All right, so 279, 280 came in.

(Plaintiff's Exhibits 279 and 280 received in evidence)

THE COURT: 281 and 282.

MS. BRILEY: No objection to 281, 282.

279, we -- this is no objection.

THE COURT: Okay, all right.

Now, does the plaintiff rest?

MR. WHITNEY: The plaintiffs rests, your Honor.

THE COURT: All right. Now, is there anything more from the defense?

MR. VELIE: Yes. Well, would you like to have the -- We have a few motions, your Honor, that we'd like to put on the to the record.

The first motion, your Honor, is under 28 United States Code, Section 1927. As the Court may recognize, this is a motion for sanctions for bringing vexatious litigation. This case has been an imposition on the Court and of course on the

Harts, number one. Plaintiffs destroyed documents after they had filed their notice of claim. The Court has already found that this was done willfully. We're going to show during our summation that this has been -- this has materially impacted and pervaded the case.

Number two, the plaintiff's narrative of the case, their basic fact theory, they represented to this Court that the company was noncompliant, but that Mr. Morrissey, aided by Mr. Campo, rode like a white knight to the rescue and fixed everything. And they knew, they knew, their witness Takemura, who is here, their witness Hugh Fryer, who is no longer here, but still works for the company, they knew that they had cause or fired, caused to be fired or fired Morrissey for total incompetence. They knew that Campo's views were extreme. They knew that Morrissey did not know anything about the regs, but had wasted millions of dollars in incompetent efforts to change everything around at the company when it had passed 13 audits and never failed a single one. I believe that it is an imposition on the court to come in and claim that this guy fixed everything, when they knew he was incompetent, and they fired him for incompetence, and we were able to bring that out on cross-examination. They never came clean with the Court with respect to this.

Number three, they did not furnish --

THE COURT: Wait. Number three? I thought that was

number two.

MR. VELIE: It was number two.

THE COURT: What was --

MR. VELIE: First is they destroyed the documents, number two, they represented the Morrissey story as being valid, when in fact they knew it was bogus.

THE COURT: Okay.

MR. VELIE: Number three, they did not furnish all of their documents to the FDA expert.

THE COURT: You mean Ms. Kuehn.

MR. VELIE: Yes.

THE COURT: Okay.

MR. VELIE: Number four, we were forced to fight through two Erb reports, and we're still fighting about this, despite the fact that this Court has held, and it's in a written opinion from the Court, that there are no Femtelle damages; that if they're right about Femtelle, all they get is that they don't have to pay the earn out that the risk of developing Femtelle was on them. This is plain from the SPA. This Court has already been through all of that in interpreting --

THE COURT: What ruling are you discussing?

MR. VELIE: When we moved to dismiss the complaint.

MR. WHITNEY: The fraud claim, your Honor, not the breach of contract claim.

MR. VELIE: We moved to dismiss everything. You read the SPA and held that what the SPA held was that the entire risk of getting Femtelle approved and Femtelle marketed was on the plaintiffs, that the risk of failure was on the plaintiffs, and that should there be a failure of Femtelle, well, then the only damages that might be considered for the plaintiffs would be that they didn't have to pay the earn out. Despite those clear rulings and clear statements in the SPA, we've had to battle at huge expense, which I tell you the Harts cannot afford, to deal with this through repeated Erb reports. The first one was dismissed when the Court insisted that it be dropped. That's our first motion, your Honor.

The second motion essentially underlies it. We believe we are entitled to a ruling that it is the law of the case that the risk of developing Femtelle is on the plaintiffs, the risk of getting Femtelle approved is on the plaintiffs; that this is clear from the SPA, and that the only damages are consequences from the failure on the part of Femtelle would be that they don't have to pay the earn out.

I think Mr. Kortmansky has another couple of motions to put on the record.

MR. KORTMANSKY: Your Honor, we also seek to strike Mr. Erb's testimony, his methodology of using a hypothetical buyer and a hypothetical seller to determine what the value was at the time of the purchase, then using a reasonable person

standard to determine what the purchase price should have been is in direct contradiction of New York law. And as decided by Judge Stein in Buckley V. Deloitte and Touche, that the opinion of an expert who reaches his conclusion independent of the actual facts must be stricken.

In addition, Mr. Erb's methodology does not comply generally with New York law, which requires that contract damages must put a plaintiff in a position it would have been if the contract had been performed as written. And you can not put the plaintiff in a better position than they would have been based on your damages calculation. And for those reasons we think that Mr. Erb's report and his testimony regarding his calculations should be struck.

Similarly --

THE COURT: Let's just pause there. When I asked him why he used a hypothetical buyer, hypothetical seller reasonable person, he said he was relying on controlling Second Circuit law. I didn't ask him to cite the case. He wasn't here as an attorney. But, Mr. Whitney, what case was he --

MR. WHITNEY: I'll get the citation for you in a moment. It's my, unfortunately, my folder is in the jury room, it will here in about a second, it's the Merrill Lynch case, it's black and white Second Circuit law that the damages for breach of representations and warranties is determined by difference between the value of the company as warranted and

the value as delivered from the point of view of a knowledgable investor with knowledge of the breaches at the time of the transaction. It's clear law, in fact the case that Mr. Kortmansky cited in his trial pretrial memo for the point that he's trying to make now actually cites that Second Circuit case as a basis for it's position.

THE COURT: Is that your colleague?

MR. WHITNEY: Yes.

THE COURT: No. It doesn't happen to be Allegheny, is it?

MR. WHITNEY: Yes, it is actually.

THE COURT: What a memory. Okay.

MR. WHITNEY: Better than mine, your Honor. So that is 500 F.3d 171, and I can read the --

THE COURT: Go ahead.

MR. WHITNEY: -- clear part. This was remanding the district court's decision. On remand, the difference between the value of GEM -- target company, GEM as warranted and its value as delivered should be calculated. GEM's value as delivered should reflect any deductions from its purchase price necessary to reflect --

THE COURT: Would you read at a speed that can be taken.

MR. WHITNEY: Sorry, your Honor. GEM's value as delivered should reflect any deductions from its purchase price

necessary to reflect the broken warranties. In other words, the district court should determine how GEM would have been valued by knowledgable investors at the time of the sale where such investors aware of any breaches proved by Allegheny. As any such damages are general rather than consequential, Allegheny is required to show reasonable certainty, the fact of damage, not its amount.

THE COURT: Okay, thank you.

MR. KORTMANSKY: Your Honor, Merrill Lynch is not relevant to the proceedings here. In Merrill Lynch the issue was that the seller had provided fraudulent financial representations. And, in fact, the gentleman that provided those fraudulent financial representations eventually went to jail as I recall from the case. And those circumstances, because breach related to fraudulent financial representations which were the sole basis on which the plaintiff in that case determined their purchase price, obviously that breach could not be remedied simply by giving the purchaser what they thought they had actually purchased. You had to come up with some other valuation for the company in that circumstance, because the financial reps and warranties regarding the finances were false.

In our case, there is no allegation -- well, there is an allegation it was false, those rep and warranties are not in the case. This is a case about a breach of a rep and warranty

related to FDA compliance. And so Mr. Erb relying on Merrill Lynch we think is improper.

THE COURT: Okay. Your final motion?

MR. KORTMANSKY: Yes, your Honor. We also believe that Mr. Ulatowski's testimony should be struck as irrelevant. His testimony only went to the success of the 2009 510(k). And what he testified to was that 2009 510(k) was destined to fail because the company simply could not provide all the information required in time. He did not testify that Femtelle was destined to fail. And, in fact, there is no rep or warranty in the contract that requires Femtelle to succeed, nor is there any rep or warranty in the contract related to the 2009 510(k). It's simply irrelevant to the issues in the case, whether the 2009 510(k) would or would not fail.

THE COURT: Thank you.

All right. I'm not going to be ruling on any of the motions. I'm going to reserve decisions on all of them and rule on the case and the motions at one time.

So with that, do you want to respond to the motion or do you want to just handle that in your summations?

MR. WHITNEY: We could handle that in the submissions, your Honor.

MS. HAGBERG: Submission?

THE COURT: Summations.

MR. WHITNEY: Oh.

THE COURT: I wasn't thinking of any more submissions.

MR. WHITNEY: I'm sorry. Yeah, then I will handle the motions that were just raised.

With regard to the first motion brought, 28 U.S.C. Section 1987, the first issue about the destruction of documents, your Honor, I believe that's been decided here. There was a finding, there was sanctions issued, there's a motion pending for fees. I don't see how that impacts the rest of the case.

With regard to the characterization of Mr. Morrissey and Sekisui's knowledge of Mr. Morrissey, all that testimony came out through the testimony of Hugh Fryer where there was clear animus between the two witnesses. I don't think that necessary reflects Sekisui's view and it certainly doesn't represent the facts of the case and the credibility of Mr. Morrissey. We believe Mr. Morrissey is a credible witness and we -- clearly the issues that he found at the time he came on in 2010, which is what we're dealing with here, is separate from anything that had arisen over the next year or two after that, which is when the dispute between Mr. Fryer and Mr. Morrissey arose.

The issue, the testimony they're referring to from Mr. Fryer was occurred late in 2011, early 2012, different time period; in fact, dealing with different Campo reports that were not even included in the record because your Honor had excluded

them. They are not referring to the May and June Campo reports that are in the record. They're referring to subsequent reports that were not part of the record here today.

In terms of the argument that documents were not furnished to Ms. Kuehn, clearly Ms. Kuehn was unaware of certain documents as a result of her testimony. Candidly, it's illogical that plaintiffs would have not provided documents to their expert and then provided it to the defendants on the hopes that somehow plaintiff's expert would testify and defendants would, I don't know, miss those documents or something like that. So from a logical standpoint, there's clearly no animus or misconduct, willful misconduct here.

And the force to fight through two Erb reports, I don't understand that argument because Mr. Erb testified. His testimony was credible. He's a qualified witness. And they didn't call any rebuttal damages expert or anything like that in response to Mr. Erb's report, certainly not a supplemental report. So Mr. Erb's testimony is part of the record and he's a credible witness. And the fact that they had to deal with his report is how it worked, you know, that's how litigation works.

THE COURT: I think you missed the point of that argument entirely. The point of that argument is if his report is based on an inappropriate legal assumption, the wrong legal standard, then none of it makes any sense because he applied

the wrong standards. So it has to do with the debate, which is we just went through about whether Merrill Lynch versus Allegheny is the right standard or not the right standard in this breach of warranty representation case as opposed to fraud case. That's the point. If you applied the wrong methodology, the whole thing should fall.

MR. VELIE: Your Honor, excuse me. Exactly it's the Femtelle argument.

THE COURT: I started to say --

MR. WHITNEY: I'm sorry, I had a different issue.

THE COURT: Femtelle argument.

MR. WHITNEY: So the law of the case argument, your Honor, they're referring to the motion to dismiss opinion that was issued in response to fraud claim that we had alleged on Femtelle. The Court's decision actually at one point explicitly noted that the fraud claim was duplicative of the breach of contract claim and that's why the fraud claim was dismissed, obviously leaving open the possibility of bringing a breach of contract claim for Femtelle which is what was done here.

In addition, the Court was not dealing with the issues that Mr. Velie is looking to have the ruling focus on now, it was dealing with whether or not there was an action for fraud for Femtelle, which is separate whether there is action for breach of contract.

Further, the ruling with regard to whatever Mr. Velie is looking to hold with regard to risk, clearly that was risk of Femtelle not taking it to market. Clearly whatever risk that Sekisui was absorbing that Femtelle making it to market was with the assumption that the representations and warranties in the stock purchase agreement are true. If the representations and warranties were false, then we're entitled to damages for the consequences of that falsity.

THE COURT: I think you're moving over now to his motion with respect to Mr. Ulatowski, because he's saying Mr. Ulatowski's testimony that the 2009 Femtelle application was destined to fail is irrelevant to anything here.

MR. WHITNEY: I thought Mr. Velie was arguing that the risk of failure was on Sekisui.

THE COURT: He was. But then you began I thought to move over to the notion that the 2009 510(k) with respect to Femtelle.

MR. WHITNEY: I will certainly address that. Just to finalize this point, we're not arguing, your Honor, that the failure to reach, to have Femtelle in the market in and of itself is a breach or that that was the defendant's responsibility. We're arguing that the defendants did not have the mandatory or the required clinical data or the design history file that the FDA wanted in order to clear Femtelle in 2007 and 2009.

THE COURT: And therefore what?

MR. WHITNEY: And, therefore, Femtelle was unable to make it to market as a result of that breach of representation and warranty, 4.1(c). So it was the resulting damage from the breach of representation and warranty that caused the harm to Femtelle. But for that breach, you know, Femtelle should have been able to make it to market since that was the impediment.

With regard to Mr. Ulatowski. Again, Mr. Ulatowski testified that Femtelle's 2009 application was destined to fail. The 2007 application failed, as the facts showed, because in part it didn't get approval because it lacks the necessary clinical data in order to reach 510(k) approval. The ADA asked for it, the Harts spent years looking for it. They didn't have it. They didn't do the test themselves. It was done in Germany and they didn't have the clinical data, and they couldn't satisfy the FDA's concerns. They refiled the application in 2009. Again, the FDA came back and said we need --

THE COURT: I know. We should get to the point. He said it's not relevant to an issue in the law so --

MR. WHITNEY: It is relevant because --

THE COURT: To what, just tell me what issue?

MR. WHITNEY: Because that the Harts represented they had all clinical data for product.

THE COURT: I'm sorry, not tying it to the 2009 510(k)

submission which he testified was destined to fail. To what issue is that so?

MR. WHITNEY: It's relevant to the -- I'm sorry, maybe I miss --

THE COURT: Ulatowski's opinion.

MR. WHITNEY: Is relevance -- I'm sorry.

THE COURT: The 2009 FDA application, 510(k) application for Femtelle is destined to fail, to what issue is that relevant, his opinion?

MR. WHITNEY: His opinion is relevant to breach of 4.14(c).

THE COURT: Thank you. All right.

MR. WHITNEY: Sorry. And the basis of Mr. Ulatowski's opinion in 2009, and the fact that the company couldn't get the data.

THE COURT: I don't need to hear all that. I'm sure it's going to be in summation. I just wanted to hear to what issue you thought the opinion was relevant to, because Mr. Velie said or Mr. Kortmansky said it's not relevant to any opinion and the issue in the case.

MR. WHITNEY: That is the issue to which it is relevant, your Honor. Oh, that's correct, your Honor, it's actually also relevant to their counterclaim, which is that we, that Sekisui did not use commercially reasonable efforts to get --

THE COURT: That's what I thought the answer was, but --

MR. WHITNEY: But, your Honor, principally it's related to affirmative claim 4.14(c).

THE COURT: Okay.

MR. WHITNEY: We talked about Mr. Kortmansky's argument with regard to Mr. Erb's methodology. We submit that's the proper --

THE COURT: You already told me that.

MR. WHITNEY: And one item I didn't note, by the way, is that in the defendant's submission to the Court on September 16th, 2013 in a letter signed by Mr. Velie, he states that breach of contract, quoting, citing to Aroneck V. Atkin, he notes that breach of contract damages are based on, quote, what knowledgable investors anticipated the future conditions and performance would be at time of alleged breach. So the defendants agree with the position several months ago, and now seem to claim otherwise.

THE COURT: Okay. As I said before, I'm going to reserve decision on all of these motions and reach all at once. Thank you.

All right. Now, are we ready for summation?

MR. WHITNEY: We have one motion, your Honor.

THE COURT: And what is your motion?

MR. WHITNEY: Well, we don't know if defendants have

rested their case yet. That was we were waiting for.

MS. BRILEY: We just wanted to enter three exhibits into the record. One is marked as defendant's Exhibit 4Q, it is from the FDA website and it contains definitions of the inspection classifications. Mr. Velie used it on voir dire of Ms. Kuehn.

THE COURT: Okay.

MS. BRILEY: And the other two are party admissions from plaintiffs and they are DX-3Z and DX-2I. They were on our exhibit list and were not objected to, but I can show them to plaintiffs. If they would like to dispute their --

THE COURT: What are they, what do they go to?

MS. BRILEY: They go to the claim regarding expired raw materials and the claim regarding the Femtelle batch records or the design history file.

THE COURT: Okay.

MR. WHITNEY: Your Honor, I mean they're statements of employees. I don't know they're corporate admissions of the company.

MS. BRILEY: Business records at any rate.

THE COURT: Probably both, all right. I think they're admissions. You don't need to be a senior person, you need to be an employee acting in the scope your employment, that's all you need for admission.

MR. WHITNEY: Okay, your Honor.

MS. BRILEY: Thank you.

THE COURT: So both are received.

(Defendant's Exhibits DX-3Z and DX-2I received in evidence)

THE COURT: I have to say to both sides that you're going to need to, each side prepare a list, a list of all the exhibits that were received in evidence from your side and either put them on a new disk or new notebook. The defense certainly doesn't need to do any more photocopy, but I don't think plaintiffs do either given all the books they've given me. I want you to give you back all your notebooks, and then just submit one set of exhibits with the table of all the exhibits received from your side and a copy of each exhibit, either on the disk or hard copy. Pretty much got it on hard copy, but that's -- I can't do that. I don't have the staff to do that effort. So after the trial just go through all these lists of exhibits received and do it, all right. I'd like that earliest possible time. I would think one day next week.

MR. KORTMANSKY: We can get that for you by Tuesday or Wednesday next week.

THE COURT: I'll give you the benefit of the doubt. Close of business Wednesday if both sides could submit the list of exhibits and copies, that would be great, all right. I don't think I need any more submissions in this case. You both submitted proposed findings of fact and conclusions of law.

The only thing that would be helpful to the Court is to resubmit the very same piece of paper annotated, so where you have a proposed finding of fact or conclusion of law, you could put, paren, see exhibits ABC, or see transcript pages ABC, so to annotate the proposed finding of fact and conclusions of law I often want post trial. I don't want more arguments and more briefs.

MR. VELIE: Your Honor, we understand that. However, some of the things that we can invite you to find as conclusions, findings of fact we learned on cross-examination, they were not in our prior submission so.

THE COURT: Then you can each put in supplemental proposed findings of fact.

MR. VELIE: Thank you, your Honor.

THE COURT: Conclusions of law along with the annotated finding of fact and conclusion of law that you submitted pretrial, but again I don't want this to take very long. I want this to remain fresh in my mind. So can you get in the proposed supplemental finding of fact and annotated had findings of fact by no later than two weeks from today, I mean it's more than I want to give but no later than two weeks from today? Today is January 17th, so no later than the 31st and earlier if you can that would be fine, but no argument, no reason to respond to each other, just annotate any supplemental proposed findings or conclusions and annotate previously

submitted, by no later than the 31st, all right?

MS. HAGBERG: Yes, your Honor.

THE COURT: Now, are we ready for summation?

MR. WHITNEY: Now we have our motion if defendants are resting.

THE COURT: Do the defendants rest? Do the defendants rest?

MR. VELIE: Yes, your Honor.

THE COURT: What's your motion?

MR. WHITNEY: We would move for judgment as a matter of law, your Honor, on their counterclaims. They've offered really no proof to support either of their claims.

THE COURT: They have two.

MR. WHITNEY: They have two. One we never even heard of in this entire case.

THE COURT: What's that?

MR. WHITNEY: It's a claim that the notice, the claim notice was deficient for the escrow.

THE COURT: I thought maybe that was being abandoned. Was that?

MR. KORTMANSKY: Your Honor, there is no point in pursuing that claim any more because of the proceedings, so.

THE COURT: That's what I thought.

MR. WHITNEY: So that one -- the second counterclaim, the commercially reasonable efforts, your Honor, commercially

reasonable efforts is an objective standard that needs to be established as to what framework it should can be evaluated in. Defendants have not done that. They've not offered any expert testimony of anyone in the industry or anything that could replace that to show what a commercially reasonable effort to bring Femtelle to market could be and what, how Sekisui's conduct could be compared against that standard. And so we submit that we would cite to in MBNA Insurance Corp. versus Patriarch Partners, which give the Lexis site is 2013 U.S. District Lexis 81473 at 141 for support, and that there the defendant's counterclaim should be dismissed as a matter of law.

MR. VELIE: I can address that in 30 seconds, your Honor. I'm looking at the SPA on page 18. And if I remember correctly, it's 2.6(d)(1). It's on page 18. It not only says, as Mr. Whitney points out, undertake commercially reasonable efforts to market and sell or cause the marketing and sale of the Femtelle product, including providing commercially reasonable personnel technical and financial resources therefore, and submitting to the FDA an analogous nongovernment and so on, it does however say, not willfully take any actions or omit to take any actions, with the intent to prevent business from meeting with Femtelle targets. And as the proof was abundantly clear, they withdrew a pending Femtelle application. We believe the proof clearly shows that they did

that to avoid an audit or possibly for tax reasons, but what's most important is they omitted thereafter to ever offer Femtelle to the FDA again, or to market it in any fashion, that this was done despite the fact that they put in their own report to their own auditors an 80 percent chance of success of getting it approved and marketed.

THE COURT: Okay. As I say, I'm going to reserve decision on all motions. I think we're ready for summation.

MS. HAGBERG: Yes, your Honor. Your Honor -- okay?

THE COURT: Yes.

MS. HAGBERG: Defendants have had three themes since this case began back in the very beginning. The first is that we didn't do it, and the second is that we did it, it wasn't so bad, and the third is even if we can't prove one or two, that's because they threw away all of the documents that it would have proved our case.

Plaintiffs have shown during the last five days that none of those arguments is true, and I'd like to address them in the order I just listed them.

First, defendant's argument that we didn't do it. Defendants argued in there opening that conditions at the company had to be okay because ADI has been inspected and audited a number of times in the period from 2004 to 2011.

But defendants also argued that the only thing the Court would hear from plaintiffs would be general anecdotal

statements about noncompliance. The documents and evidence that we presented, however, showed that that was just not the case. The documents painted a picture of a company that was lacking the rudimentary fundamentals of compliance.

Now, Mr. Morrissey, who spent decades in the medical device field, including being senior head of manufacturing at Siemens, arrived at ADI in March, 2010. And he explained all of the problems that confronted him when he arrived, and that those problems even in the first weeks were so pervasive and systemic, that they affected hundreds of the products that were on the market. He commented that those problems resulted from the lack of knowledge of FDA regulations at the company, the lack of proper documents to support products that were currently on the market, and the fundamental disregard or lack of knowledge of how a company should be run in order to meet the regulatory structure that applies to medical device manufacturers.

And I don't think there is any dispute in this case that 21 CFR 820 and its sub parts applies to ADI.

So Morrissey arrives on his first day of work. He goes in the office that gets assigned to him and he finds this pile of records. And this is his story. He picks them up, he does an initial review and he sees they're out of specification. They reveal the use of expired materials, and they didn't reflect the proper quality control oversight. And

if you would put up 158. He said I discovered batch records that had data in them that didn't meet specification. I found that a number of raw materials had been expired. I reviewed records that weren't approved or QA released before they went into the market. And why is that a problem? It's a problem because the regulations require that product is released by QA before an IVD goes into the market to ensure that they meet specifications. And Ms. Kuehn, and I believe also Mr. Fryer testified and maybe even Ms. Gaikwad, that these products we're talking about are testing products. They go to clinics, they go to hospitals and doctors, clinicians use them to determine whether a patient needs a certain treatment, a certain medication, and Mr. Morrissey took those responsibilities very seriously as you saw, your Honor.

He further described those records a little later in his testimony. He stated that there was a stack of probably 70 or 100 records in his office of product that was out in the field that hadn't been processed appropriately. And yes, your Honor, he didn't do a recall, and defendants make a big deal about that. But they suspended the product release and they waited until they could confirm that the product could be released before they let it out into the market. And defendants try to say that's no big deal. But they don't know. No one could tell what the qualifications of the product were and what the impact that they might have of false diagnosis or

anything else. And releasing product, IVD product that contains expired materials is a huge issue. A product that has materials is expired materials is considered adulterated under 21 U.S.C. 321 and the other provisions following. So that action alone constitutes a breach of three of the four representations and warranties in the SPA that defendants breached. And to say that that is not a material breach is not, has not been disputed by the defendants to cross examination of Mr. Morrissey, Mr. Fryer and Ms. Kuehn. Efforts by defense to say, well, FDA didn't know this or INTERTEK still passed us are unavailing. And just to reduce this to a very simplistic analogy. If I'm driving 80 miles an hour in a 30-mile zone, I'm not compliant with the speed limit, and the fact that I don't get caught that doesn't make a difference. And Mr. Ulatowski and Ms. Kuehn said that a company has an obligation to comply with the regulation. It's not a matter of whether someone notices the noncompliance or not. It's a matter of whether you are compliant. And Ms. Kuehn put the slide up with management control in the center and said management, and that's at the executive level.

THE COURT: Well, the difference between your analogy and what happened here is if you're going 80 in a 30-mile zone and you don't get caught, that doesn't mean you were compliant with the speed limit. But here you actually have inspections and audits where people come from the outside and are looking

at all parts of the company and interviewing people, reviewing records and using their eyes and ears and actually looking to evaluate those very areas of compliance, and then they don't find something wrong. So it's a little different than the fact there was no policeman in your speed zone.

MS. HAGBERG: I understand, your Honor. But I think my analogy is more to the point. The fact that you know they come in, they spend a day, they spend two days and they don't find anything.

THE COURT: I don't know. Two days is a lot of time.

MS. HAGBERG: But each one of these reports, and by that I mean the main ones, the FDA inspection, they did find violations. They did find deficiencies. And so they didn't get a clean record, and they didn't pass. And so to say so what, they improved it, they improved the things that were identified when the FDA was there. But that didn't mean there weren't other problems that FDA didn't notice. And in fact our fact witnesses who were at the company during the entire relevant time period said this is this was the way the company operated, and it's driving force was to get the product to the customer, as quickly as possible. And there is an exhibit PTX-187. And again I'm reading this, you know, without the context of Mr. Hart, but he's saying there is a back order on 885, so we're looking sales --

THE COURT: Wait, I'm sorry. Where are you?

MS. HAGBERG: Sure.

THE COURT: I don't know where you're reading.

MS. HAGBERG: It says the first sentence, I've been look at the back order situation.

THE COURT: Oh.

MS. HAGBERG: So he says yes, you know, users need this. But he also says if we can't make a perfect or sufficiently perfect 885, then at least surely we could stock a less than perfect but acceptable one. And Ms. Gaikwad said, this is the way the company was run. Your Honor, it wasn't until Mr. Morrissey came in who had 35 or whatever years of background in FDA compliance, that the individuals who worked at ADI were, came to understand that they weren't doing business the way they should have been.

THE COURT: You know, you make light or you did through when Mr. Whitney's motion, Dr. Fryer's criticism of Mr. Morrissey as if to say, well, those guys were just in a personal feud. But Fryer was an impressive witness. He had a lot of credentials. And he, frankly, thought that Morrissey was an extremist and he was misinterpreting the regs and he had developed some super super perfection standard that was not appropriate. He said you don't know anything about what you're writing about. I mean, you're asking me to ignore that to say oh, boys will be boys and they're just fighting and, you know, that's how guys are. But, you know, and I understand. But

Fryer has credentials, and he was serious about his criticism at the time. He said Morrissey is way out and he doesn't like when he's involved with Campo, who is also way out. And there are real documents at the time of the Christmas correspondence and just after New Year's where really points out this is not the standard, this is not a standard you're -- you know, you're sort of having a -- you know what a rule book strike is -- sort of a rule book strike, you're setting a standard nobody meets, it's super perfection and its costing us millions and wasting our time. You're saying to me don't pay attention to Fryer's criticism, it was just a spat. I have trouble with that.

MS. HAGBERG: But, your Honor, in context I'd like to put that in date context if I may.

THE COURT: Well, I know the spat wasn't until December of 2011, January 2012. But basically he's saying Morrissey shouldn't be trusted, he was a bit of a nut and he teamed up about this guy Campo who he then went off with to make money, neither of them knew what they were doing really and they were extremist just off the spectrum.

MS. HAGBERG: You did hear Mr. Morrissey's testimony.

THE COURT: I did. But if I weigh way Morrissey versus Fryer, that's what I'm left with. I will have to do it. One of them is credible on that issue, maybe the other one isn't.

MS. HAGBERG: I think the other thing that's important

to realize about that testimony, your Honor, is that there had been subsequent, the notice letter goes out in October 2010, and as you recall --

THE COURT: I'm sorry, which notice letter?

MS. HAGBERG: The notice letter under the SPA that, letting plaintiff, defendants know about the claim.

THE COURT: Oh that, yes.

MS. HAGBERG: So in the spring of 2010 when Mr. Fryer first starts working with Mr. Morrissey, he's working with Mr. Morrissey and Mr. Campo together and they're trying to come up with a plan to fix the company.

THE COURT: Yes.

MS. HAGBERG: There is no, there was no objection at that time by Mr. Fryer to what Mr. Campo or Mr. Morrissey was doing. Two more reports come out that where they were excluded, your Honor, because they, by that point Mr. Campo had been retained by --

THE COURT: I --

MS. HAGBERG: -- morgan Lewis.

THE COURT: I remember.

MS. HAGBERG: That starts a fight in the company, as Mr. Fryer acknowledged, and it was who was going to be able to take over the lead of the company. And on rebuttal, Mr. Fryer stated that in fact, Mr. Morrissey's knowledge of compliance was significantly more substantial than his, and he stated --

THE COURT: He back tracked and tried to save the day. But I can't discount his written contemporaneous documents. I can't discount the fact Mr. Morrissey was in fact terminated and terminated based on alleged incompetence. And he then in the throws of litigation wants to rehabilitate him and say, oh, he knows so much about compliance, when earlier he said he was an idiot who didn't know what he was talking about. I'm just saying it's not an easy argument that you have in terms of the credibility of Morrissey, but -- okay, I didn't really mean to interrupt. I just wanted to have the question and answer opportunity and I had it.

MS. HAGBERG: And I would just go onto add that regardless of the fight that's going on there, there are contemporaneous records, there are batch records, there are --

THE COURT: Oh, of all the deficiencies.

MS. HAGBERG: Of all --

THE COURT: Oh, sure, we'll get to that.

MS. HAGBERG: That existed in that time period.

THE COURT: For sure. And your witness --

MS. HAGBERG: Miss Gaikwad.

THE COURT: Kuehn, certainly collected all that.

MS. HAGBERG: Yes, your Honor. So regardless of whatever caused those December Christmas day New Year's e-mails, there is that fact evidence that shows, and Ms. Kuehn pointed out where there were deficiencies.

THE COURT: Yes.

MS. HAGBERG: And it doesn't have to be --

THE COURT: I think that would bring us inevitably to materiality, because I don't know what Mr. Velie plans to say in summation, but there certainly were deficiencies at least I'm convinced, there were areas of things weren't perfect that's for sure. I think he's going to end up arguing materiality, but we'll see.

(Continued on next page)

MS. HAGBERG: But I just want to point out one other point, your Honor, that we think is kind of a theme and critical here, is that as Ms. Kuehn stated, that Section 820 of Title 21 of the CFR, it applies to every product every time. So it's not as if you can squeak by or you can get some product out and if it's got a problem, you know, okay, well most of it's okay. That's not what the standards require. And I think all of our witnesses with knowledge and in particular, Mr. Ulatowski, had said why the FDA takes this so seriously.

So if I could show Plaintiff's Exhibit 213. So these are the problems that were identified by Mr. Morrissey after he had been in the office for a relatively short time and the actions that needed to be improved, all of the different areas of the company that needed to be improved. And again, your Honor, I don't think that defendants have successfully shown that each one of these separate categories of problems that Ms. Kuehn defined is not material. I think that they have made a general blanket statement and tried to challenge it on a pretty superficial high level, but when you look at each one of these problems and the documents that we have submitted to support them, I believe that defendants have not made any kind of a defense that the company was acting within the requirements of 820, of Section 820.

So if we could put up PTX 235.

THE COURT: If they were out of compliance with 820,

then what was their duty under the SPA to disclose that?

MS. HAGBERG: The breaches of reps and warranty, your Honor, are in 412, 414(a), well, the reps and warranties I should say were in 412, 414(a), 414(c) and 414(d).

THE COURT: And did one of those talk about being in compliance with FDA regs?

MS. HAGBERG: Yes, they did, your Honor. And I'm just trying to find it here in my outline. 414(a), your Honor, under 414(a), Harts warranted that since January 1, 2006 ADI has been in compliance -- I'm paraphrasing -- in all material respects with all applicable laws, and laws is a pretty broadly defined term in the SPA and certainly includes CFR regulations. It would also be a breach of 414(c) and I would submit a material breach because 414, in that provision the Harts warranted to all records relating to the company's products including design history files, medical device reports, data relating to non-clinical and clinical testing have been maintained in accordance with, quotes, "sound business practice." But, again, as it turned out that was just not the case. Again, your Honor, this warranty applied not just to the core products or the products that were then on the market but it also applies to Femtelle.

THE COURT: You're using the word Femtelle?

MS. HAGBERG: Products is defined in another section of the agreement, your Honor.

THE COURT: And uses the word Femtelle?

MS. HAGBERG: I'm sorry, it doesn't use the word products but it's a pretty broad -- can we put up the definition of products? I can't give you the citation. I'm sorry, we'll put it in a --

THE COURT: All right.

MS. HAGBERG: And as we've seen there are categories of documents that didn't exist or weren't in the form that they needed and the witnesses testified about the lack of batch records or batch records that had information scratched out, they were missing expiration dates there were no design history files, there were maybe pieces here and there but nothing in the context to fit what a design history file is supposed to disclose.

And Harts also warranted and this is also relevant to the breaches that under 414D no products had been misbranded or adulterated within the meaning of the federal Food Drug and Cosmetic Act of 321 and that also since January 21, 2006 they had not received any correspondence or other communication from FDA, the subject matter of which could be reasonably expected to have a material adverse effect.

THE COURT: Since when?

MS. HAGBERG: Since January 1, 2006. That's why the relevant time period is January 2006 to the end of 2009.

THE COURT: And what disputes that? What did they

receive since January 1, 2006?

MS. HAGBERG: There was correspondence with FDA about Femtelle during this time period that was not disclosed. And there was also, your Honor, under the first part of 14(d) as I stated a few minutes ago if a product is released on the market and it has expired materials or doesn't have the proper documentation then it's considered adulterated and that would be a breach and we would submit that there's no question that that's a material breach of 414(d).

I skipped ahead there. I just want to make sure I don't have anything else.

THE COURT: All right.

MS. HAGBERG: And just in terms of, again, on expiration dates, your Honor, Mr. Fryer who joined the company in 2006 testified during the trial that, quote, and maybe you could call this up, page 271 at lines 23 to 25? He said we made what we considered to be educated guesses on what the expirations were.

We also heard about problems with the quality system and the lack of overall implementation of that system. And we heard witnesses say we have significant deficiencies in our quality system. Mr. Morrissey in PTX 172 stated, "We had the issues with batch records and using expired materials but we also had no CAPA system. So we weren't investigating technical and customer issues."

I'm sorry, your Honor, he's looking at PTX 172 and that's from the transcript at page 168 lines 19 to 23.

Mr. Ulatowski also testified about the importance of quality system regulation. And this is in the transcript at page 427, lines 20 to 428 lines 1 and 2. And he stated, he explains that regulation speaks to the design process for a medical device and that the regulation moves into the requirements regarding manufacturing of the device and also addresses the marketing of the device, monitoring the device in terms of complaints and problems. And basically it covers a life cycle of a medical device. And so these documents are not something that if they don't exist or if they're not complete or that they're missing portions of them or that they have blanks that they can be considered to be, well, it's a little off but not so much that it's a material breach.

Another problem was the lack of training as required by 31 CFR 820. Both Ms. Gaikwad and Mr. Fryer testified that when they got there they were handed a stack of forms, the GEN 41, other forms that were introduced into evidence and testified about during the trial this week, your Honor, and they sat down at the table and read them. Mr. Fryer, although he had a very impressive legal background and had worked in a couple of life sciences companies, he had spent a few years prior to joining ADI as a carpenter and the six months or a year before he had worked as a medical writer. And so he

really had no knowledge of what the regulations require. He went through it very quickly, your Honor, but he said I was a carpenter and then I was a medical writer. So he spent this time period and he comes in, he's a research scientists and he's given these documents and said okay, go develop products. Bhavna Gaikwad said the same thing; I was given these documents I was told to read them, but there was no QSR system, no detail and specific procedures, there was just a series of other documents that were unclear and gave no guidance of the specific procedures and processes for which they were intended.

Ms. Gaikwad testified at 524, lines 5 through 10 -- can you put the question up there too, Mr. Fisher?

"Q. Did Ms. Ayres have meetings with employees where she tried to talk about training?

"A. Yes. There used to be a group of individuals who used to be called, typically a training used to be reading the SOP in front of a group of individuals and if anybody had any questions they were supposed to ask -- I don't know, none of the employees felt that the training was sufficient enough to apply it on their daily job."

We also heard from Mr. Fryer about the lack of DHF's, design history files, and those are required under 21 CFR 820.30 and defendant specifically represented that they had those in Section 4.1(c), 414(c) of the SPA. Mr. Fryer and Ms. Bhavna Gaikwad both testified that in the absence of any

forms and any direction from management they both kept notes in their laboratory notebooks. They followed no procedure or protocols and working on the research and development of new product. Ms. Gaikwad explained, well, sometimes there was a system in place but it wasn't a hard and fast rule. Sometimes people wrote, sometimes people did not write. I mean, there was nothing like somebody supervised that or was wanting that the lab notebooks were looked at. And she said the conditions remained that way from 2002 when she joined the company until after the acquisition.

Mr. Fryer testified that design history files did not exist and they couldn't be found and as a result in 2010 he and several members of his group had to create those design history files. He testified that because it was such a massive undertaking the company prioritized recreating the DHF's in 2010 and he worked with a number of people at the company to prioritize the review based on need in the marketplace as well as the volume of sales that were had for each of these products.

Fryer also reviewed for us, if you recall, an example of the design history file that had been created in 2010 for product 860 Imubind tPA ELISA and that's PTX 60. He explained that the record he created had to be created by a collection -- PTX 60 is the batch document history file that was created and he said it had to be created by going through a collection of

documents that he could find anywhere in the company and some of those, in fact many of those came from Femtelle submissions that had been made and because of those they were still around.

And we also heard from Mr. Fryer that these DHF's that they created could not have been created in the way they should have been done because the files should have contained the records from the stage at which the design began right up through its release to the market with each step being reviewed for quality purposes along the way.

Ms. Gaikwad also noted that although she was in R and D she would make kits sitting at her desk that were released directly into the market and even if a transfer was made to manufacturing there was no validation or procedures in place to insure that the transfer from design to manufacture was successful. And defendants argued, well, those were RUO's, weren't they Ms. Gaikwad, and that's research use only and, yes, they were RUO's with respect to most of them although she also worked on 102201 which was ultimately a Femtelle -- 101201 which is ultimately released in the market as an IVD. But even if they were RUO's the idea of somebody sitting there and putting a kit together and sending it off without anyone reviewing it or anyone in manufacturing being involved just shows a company where following procedures didn't matter.

We also looked at examples of preacquisition batch records because that's another critical component. And

Mr. Fryer walked us through one that was created in 2007 for Quest Diagnostics and that's PTX 210. And we saw a record that was riddled with crossouts and with missing expiration dates. The records showed the use of SOPs that were not associated with the manufacture of that kit and Mr. Fryer, unfortunately, your Honor, in quite a detailed way went through a number of pages of that document showing everywhere it was not compliant. And in fact he testified that the final product was not quality reviewed until several months after its release. Even more, although the product was set to expire in a year as Mr. Fryer testified ADI wrote to Quest in January 2008 and extended the expiration date and they've conducted no verification that it was safe to do so and when they subsequently attempted to verify it, it failed.

We also saw another example of batch record and that's PTX 211, where expiration dates were changed haphazardly by adding an A with no confirmation or validation testing and Mr. Fryer said he saw instances where not only A, but B, C and D were added further extending the dates. He testified these were not isolated incidents but many of the batch records he worked with or that he remediated in 2010 contained the same types of problems. We think the record is clear that ADI's quality system was materially non-compliant during the relevant period.

That brings me to the second point that I think we've

just shown, that even if we did it, it wasn't so bad, and I think this testimony and the documents show that it was, it was bad. So what defendants point to again are these audits and the FDA inspections and they say that because those were passed we were okay. But those were passed and done in the time period when all of these problems that the fact witnesses identified existed. Not all of them, your Honor, I'm just saying some of them, and the auditors didn't find those, Intertek didn't find those and they found other things, though. In all of the audits, in each of the significant audits and by that I'm kind of eliminating the customer audits because I don't think that Ms. Kuehn puts them in the same category as the Intertek and the FDA inspections. And Mr. Morrissey noted that with Intertek the audited party had significant control on what the auditor hears. He said that by controlling or suggesting the questions the audited company can also control the outcome. And as he testified, and this is at page 210 and 211 --

THE COURT: Which witness was this?

MS. HAGBERG: This was Mr. Morrissey. The biggest difference between FDA and Intertek, and you can read that from the context, is we hire Intertek and they do an audit for our company. In response to the question of whether Intertek goes through and reviews every part of the company every time he bluntly responded no. And, your Honor, your Honor asked

Mr. Morrissey is Intertek a private company and has competitors in the field and Mr. Morrissey's response to that was yes.

The FDA did issue a warning letter in 2004 and one of the things that it said was that ADI lacked a CAPA system. And when the FDA returned the following year FDI signed off on it and thought that ADI as represented by ADI had put procedures in place to address the concerns, but FDA made three additional observations which ADI then also allegedly addressed. And again, the FDA never came back. They never came and inspected this 30-employee company, whatever it was at that time, in Connecticut, and defendants make a big deal about the fact that well, we didn't get audited again. But the big deal is that you have to be compliant. It's not that you didn't get audited. The big deal is are you compliant. And while ADI may have addressed some of FDA's concerns that they noted in 2004 and 2005, it was clear from what Mr. Morrissey uncovered in 2010 and from what Mr. Fryer and Ms. Gaikwad acknowledged were going on during the relevant period that the procedures ADI put in place were not regularly followed. And as Ms. Kuehn testified the failure to follow procedures is not immaterial. And again, she said at 633, line 25 to 634, line 2, the QSR system is meant to insure that your device, every device, every test, every time, is made the exact same way that it was, that quality is designed into that.

When FDA came back in 2011 Mr. Morrissey testified

that Sekisui was already working to remediate its problems for a year. He told the FDA of the past issues that had existed and he told the FDA that ADI was fixing it. But the FDA still found that there was a problem with the company and notably that ADI did not have a CAPA system in place prior to 2010 which was the same problem identified by the FDA in 2004 and also identified by Intertek.

And despite that, each of the audits resulted in observations being made. While the 2004 FDA inspection resulted in a deficiency letter which identified issues those issues were continuing to be fixed in 2010 and 2011 after Sekisui had taken over control of the company and Mr. Hart had left the company or at least had stopped coming into work.

Mr. Takemura explained that Sekisui relied on the representations and warranties in the SPA and they expected to be purchasing a compliant program, company, and that was important to them. We told the Court and I think we've just gone through previously, your Honor asked me about the reps and which ones we believed were breached and I think I've already covered that.

THE COURT: You have, yes. So maybe you're up to damages.

MS. HAGBERG: I have one more thing to talk about before I get to damages. I'd like to talk about Femtelle. Picking on Mr. Takemura again here. He testified that Femtelle

was critical to the transaction. Oh, your Honor, I just want to call your attention to one other provision of the SPA and that is Article 9.1 and that provision states that notwithstanding any right of any party, whether or not exercised, to investigate the affairs or the accuracy of the representations and warranties contained herein or of any other party hereto, each party hereto has the right to fully rely -- to rely fully on the representations, warranties, covenants and agreements of each other party contained herein.

So going back to Femtelle. As Jeff Ellis' testimony noted, prior to initiating contact with Sekisui and after unsuccessfully shopping ADI for almost a year CrossTree revised the confidential memorandum to push up the value of Femtelle and show that Femtelle was by far the most potentially profitable product in ADI's line. And Mr. Takemura explained that the only way they could get board approval for the acquisition was by including the projected value of Femtelle sales into the calculation of the projected operating profit. And Sekisui did an analysis confirming that the purchase price without Femtelle was potentially viable and that was that third right hand bar in the upper right-hand corner of Exhibit 49, your Honor, that Mr. Velie was -- I'm sorry, Mr. Kortmansky was directing Mr. Erb's testimony to this morning.

But what Mr. Takemura said was yes, they did an analysis without potential, without Femtelle and it was

potentially viable but the full analysis prepared for the board showed that Femtelle was an important component of the purchase price and it let them meet the board's acquisition requirements of a certain level of projected income, and that they could not have done the deal and paid 25.5 million if it were not for Femtelle.

Even with Femtelle, your Honor, defendants argue that --

But Femtelle was not the product that it was warranted to be, and Mr. Velie argued in his opening that Femtelle was not destined to fail and he says that based solely on the fact, I think, that Mr. Ulatowski did not opine on whether another future application might succeed, but plaintiffs introduced significant evidence showing the problem with both the 2000 application and the 2009 Femtelle submission -- 2007 submission and the 2009 submission. Mr. Ulatowski told us with respect to the 2007 application that, quote, and this is at 434, lines 14 through 19, the IVD group, and that's the IVD group at FDA, more often than not liked to have the raw data in order to conduct their own analysis of information because historically FDA found that applicants may err in their analyses or may not focus in on important aspects. FDA had an interest in manipulating the data itself and that's why these requests were made.

That information and other requested information was

not provided in connection with the 2007 submission, despite getting two additional extensions, and when the deadline passed FDA deemed that the application had lapsed.

And if we could put Exhibit 42 up. Mr. Ulatowski reviewed this Exhibit 42 and testified that this indicated that they still had a need for the data and what he said was the data they needed was source data, line data, the background data for the studies that had been submitted. I'm sorry, your Honor, I don't have it highlighted. Is that PTX 43?

THE COURT: You said 42, didn't you?

MS. HAGBERG: I did say 42. I just can't see it from here, your Honor. I want 42. I don't see it there, your Honor. "I hope that we can work this out. We are at the end of the 510(k) process with the FDA and have already submitted the graphs and tables. FDA will surely ask us how could we submit the graphs and tables of the clinical studies without having the raw data behind the graphs and tables. This will look very bad."

And then Mr. Ulatowski looked at PTX 43 and in this communication which went from Robert Greenfield -- your Honor, I'm afraid I have the -- oh, yes, from Robert Greenfield to Manfred Schmidt, who was involved in the studies in Germany, with copies to David Teicher, Mamoru Koseki and Richard Hart, Mr. Greenfield, who was in the preacquisition company director of R and D, one of the directors in charge of the Femtelle

application and one of Richard's Hart's executive team, noted in his May 2010 e-mail that without patient data from one of the German studies, and if you can highlight paragraph 3 -- I'm sorry, paragraph four. "It is quite possible that because of the this the analysis will fail and we will have no" -- that's one of the clinical studies -- "to present to the FDA that is valid. I cannot do anything about this. If this happens the 510(k) will not move forward and we may have to abandon the project. Femtelle has a good chance of failing in the U.S. We may only be able to market it as an IVD in Europe and CE."

He noted a later e-mail from PTX 39 --

THE COURT: I'm sorry, we're going to have to move over to damages. It's just getting too late.

MS. HAGBERG: Sorry, your Honor. Let me add just one more. As a result of all of these problems, Ulatowski concluded that the 2009 submission was destined to fail and with respect to management's decision ultimately to withdraw the pending application, Mr. Ulatowski testified if I were management there I would have made the same choice.

As Mr. Fryer testified, ADI continued but was ultimately not successful in locating the clinical data, and they also couldn't locate and recreate the batch records that FDA had asked them for and they were having problems with other types of data as well. Accordingly, the company ultimately made the commercially reasonable decision not to pursue a third

submission.

I'll turn now to damages, your Honor.

THE COURT: Okay.

MS. HAGBERG: Shortly after the closing, KPMG conducted an independent valuation of the company for financial and tax purposes. This was an unbiased, thorough and legally required analysis by a respected accounting firm of the value of the assets and you heard Mr., your Honor heard Mr. Erb testifying about this this morning. And the value of the assets is reflected in the 25.5 million purchase price. That projection for the valuation of Femtelle, the financial projections for the valuation of Femtelle were provided to KPMG by Richard Hart who was the CEO of the company and they were based on the CrossTree confidential memorandum. The projections for ADI's current products were also based on the CrossTree memorandum prepared by preacquisition management which were confirmed with CrossTree and Hart following the acquisition. Using this information KPMG was able to allocate a fair value of ADI's assets within the bounds of the purchase price. And we heard Mr. Erb with decades of real world experience valuing companies with Goldman Sachs and others and he testified that he looked at PPA for the determination that Femtelle was valued at approximately 7 million of the purchase price.

THE COURT: The only problem with that argument is

what was brought out on cross that the SPA says that anything preclosing is superseded and nothing in any of those materials should be relied upon. So if KPMG relied on the confidential memorandum and shouldn't have, does that wipe out that valuation?

MS. HAGBERG: Your Honor, I don't think it does wipe out that valuation. Mr. Erb looked at it as the basic, the best, he wasn't using it -- that kind of a representation is based on protecting KPMG from liability for --

THE COURT: No, it's in the SPA.

MS. HAGBERG: In the SPA.

THE COURT: The SPA says anything said before this closing doesn't count any longer, it's over.

MS. HAGBERG: Yes and that was in one of the reps represented to the financial breach, your Honor. That's what it related to and we're not contesting a financial breach here.

THE COURT: I'm sorry, I don't really understand that answer. What it says in the SPA, anything that's said up to this closing cannot be relied on, must be discounted and then KPMG relies on a confidential memorandum in relation to this valuation and then it says anything can change in the next eight months too. It was made before the closing, which of course was made in 2008 which wasn't a good year financially. All right. I don't want to argue, I just wanted to point that out.

MS. HAGBERG: But Mr. Erb did say that Hart provided that after it was signed and he also said the information Mr. Hart provided was after that date.

Taking into account the representations and warranty breaches, you heard Mr. Erb testify that he made alternative projections using the same type of data and techniques that a knowledgeable investor would use and determined the value of Femtelle and current products within the company as it was actually delivered. In other words, non-compliant with FDA regulations and lacking the necessary clinical data and design history files to bring Femtelle to market.

He also, after reviewing the SPA, the financials of the company and other information that was available at the time of the acquisition as well as from speaking with industry experts, Mr. Ulatowski and Ms. Kuehn, along with company employees and management, he concluded that the value of Femtelle as delivered had a slim chance of FDA approval and had years and millions of dollars to go due to the need for additional clinical trials or at least data that would replace the data that could not be found.

He also calculated the value of current products using the same methodology, given the impact of non-compliance with the FDA regulations at 6.23 million. And, finally, Mr. Erb consulted with Ms. Kuehn, confirmed by the testimony of Mr. Morrissey, and concluded that the expected cost to

remediate ADI's numerous deficiencies would be two to three million dollars over two to three years which he conservatively discounted applying the same discounts that he applied at every level to be 1.4 million as at the time of closing. Taken together Mr. Erb concluded that the value of ADI was delivered was just over $13 million resulting in 12.183 million in damages to Sekisui.

And I just very briefly want to address the counterclaims, your Honor.

THE COURT: There's only one counterclaim.

MS. HAGBERG: Oh, counterclaim. We heard Mr. Velie this afternoon saying that we had, that they had shown certain things with respect to the counterclaim but the one issue that defendants have not shown is what is a commercially reasonable effort and I'm not going to dwell on that --

THE COURT: Good.

MS. HAGBERG: Because Mr. Whitney -- it's a long week, your Honor, sorry -- who are you? Mr. Whitney testified about that so I don't think I need to cover it.

THE COURT: Not testified, but he certainly spoke about it. Okay.

MS. HAGBERG: Based on that lack of evidence we believe that plaintiffs are entitled to have defendant's counterclaim for the earnout dismissed.

THE COURT: Okay.

MS. HAGBERG: Thank you, your Honor.

THE COURT: Thank you. Now, wait, Mr. Velie, I'm very anxious to hear you, but I need to stretch just to be sure that I'm awake and aware and listen to every word. So let's try to keep this break to five minutes but I could use the five minutes just to stand up and walk around.

(Recess)

MR. VELIE: May it please the Court. There are a lot of things to talk about. Let me just start with a couple of things that might put the entire thing in context. Just a moment ago near the very end of her summation Ms. Hagberg said Femtelle was not the product it was warranted to be. As your Honor must know by now, there wasn't a single warranty in the SPA regarding Femtelle or its possibility of success or its value. In fact, any projections with respect to it were expressly disclaimed. We'll just start with that.

Second, and this has to do with the credibility of the entire presentation. The plaintiffs have scattered a lot of marbles and expect us to pick them all up. There may be, I don't know, 20 or 30 different things that their expert talked about and Ms. Hagberg talked about that are, she, one or the other of them claims might be a non-conformity and Ms. Hagberg claims is a material non-conformity. I did not hear Ms. Kuehn say that, but perhaps she did. But let's just take CAPAs. How many times have CAPAs come up in this case and they came up in

the summation again. The plaintiff's claim is that there were no CAPAs during the relevant period but we saw there were CAPAs. In the letter responding to the FDA in 2011 the FDA had mistakenly written down there's no documentation of CAPAs between I think 2006 and 2010 and the company, Sekisui, Mr. Morrissey prepared this letter too. He said oh, no, you're wrong about that, there were CAPAs during this period they were just decentralized and he gave some examples of where they were. However, you don't have to take Mr. Morrissey's word for this.

There was an Intertek audit on January 10, 2006. It's in evidence, Defendant's Exhibit M. It was a documentation review, one and a half days. They reviewed the documentation for one and a half days in January of 2006. Actually, they did it from March 23, 2006 through March 24, 2006, right in the middle of the relevant period. Do you think if Intertek had seen no CAPAs they might have said something? Nothing is noted. This is the audit itself, I'm told, on page ending 354 in Exhibit M --

THE COURT: M or N?

MR. VELIE: M as in Mary.

MS. BRILEY: No, that's L, DX L.

MR. VELIE: I'm sorry. The first thing I showed you M as in Mary is the document review immediately followed by an audit, is that correct?

MS. BRILEY: No, the one -- DX L is the document audit. The document audit is noted in the cover letter to the on-site audit that followed the document on it by a month. The on-site audit was in April 2006. The document audit was in March of 2006 and the cover letter references both.

MR. VELIE: DX L is the latter? The actual letter itself. Here's what it says at page 354 at the end. "8.52, corrective action. Does the organization take action to eliminate the cause of non-conformities in order to prevent recurrence and are corrective actions appropriate to the effects of the non-conformities encountered? Yes." And it's initialed by the auditor. There are CAPAs. They saw them. They were there for a day and a half.

There's another, I believe this is an Intertek audit -- is this the same document? Okay, I'm going, I'm sorry, your Honor, I'm going back to DX M as in Mary. On page 3 of 4, the auditor notes noteworthy positive observations regarding the implementation and effectiveness of the management system. Quote, "Good use of customer complaints, internal audits, corrective actions, preventive actions and management review to continually improve."

I think we can lay to rest the claim that there were no CAPAs. Apparently there were no CAPAs presented to Ms. Kuehn, but I don't know why that would be. She doesn't know why that would be and it doesn't prove anything. In fact,

Mr. Morrissey says that there were none to be seen simply to be false.

There's been a contention here that there are missing design history files. Well, everybody agrees that you can't get a 510(k) without design history files. In fact, that's the whole business of their saying Femtelle wouldn't pass in 2009 because a piece of the design history file is missing, a certain batch record from twenty years before. Okay? So you need DHF's to get 510(k)s. All of the products they were selling had 510(k)s. There were design history files for every last one of these and they were reviewed by the FDA. Now, apparently Mr. Morrissey thought it was important to put these all in one binder instead of having them in different places like lab notebooks. That's nice, but that doesn't mean any non-compliance.

There was some reference to Bhavna Gaikwad's testimony. Number one, product 101201. Was there a problem because she had lab notebooks? Of course not. It got 510(k) approval, which means the FDA, as it almost certainly did, looked into the design history of this thing and said all right, you got it, we're great.

It is important to note that Ms. Gaikwad, and for that matter, Mr. Fryer, were research scientists, by and large, perhaps exclusively, except to the extent that Mr. Fryer noted otherwise, they worked only in the research department.

They're working on research use only products. You can sell those, and as Ms. Kuehn told us today you can sell them, just label them research use only, that's all the customer can use them for and they are not covered by the quality system regulations. They are irrelevant to the QSRs. So everything you heard from Ms. Gaikwad that said, oh, I didn't do this and I didn't do that, whatever she said she didn't do, it doesn't matter. She wasn't obligated to do it in accordance with the QSRs to the extent that she was working on research use only materials.

Your Honor put your finger right on a critical issue with respect to the documents that were missing from Ms. Kuehn. I believe you asked this. I'm scrambling to write notes during summation but I think I've got this in the right context. The issue is the materiality of the various things pointed out by Ms. Kuehn and for that matter by the anecdotal evidence of some of the witnesses. It's not only materiality, it's context, and I covered this with Ms. Kuehn and she was kind enough to tell me she has no idea how many documents were missing. She was honest enough to say, look, this makes me less certain than I was, but she also said context is all. What can possibly that mean except this?

Okay, on day one you've got a document that's terrible. On day two they might have corrected it. That's compliance. That's the one thing that we're clear on and every

witness in the case who talked about it is, you don't have to be perfect, you have to have a system that addresses imperfections as they come up, and that's what we can't tell here because we'd have a totally incomplete data set. So that everything, virtually everything that Ms. Kuehn told us I can't tell you, she couldn't tell you, the plaintiff's lawyers couldn't tell you if two days later that thing wasn't fixed or a week later or in due course. We just don't know. Accordingly, on the context the plaintiffs have failed to meet their burden of proof with respect to this very important matter.

In short, your Honor, it's impossible for us to address every single little dinky claim and even major claims that these plaintiffs have raised. There's an incomplete data set. We're not the company, we don't have the records. Wherever we could, we showed you they were wrong. I showed Ms. Kuehn in one case she was talking about nonconforming, NCR's, non-conforming reports or non-conformity reports, whatever the acronym is. I said that's good compliance, isn't it? She said, yes, of course. That's not evidence of something bad. In another instance she had misread the document she was saying was so terrible. She had put it up on the screen and said I don't understand this but this is not compliant. And when we read it together and the Court read it, it was obvious what it was saying, it was compliant. And she

said, well, okay, you're right about that, show me another one. Okay, show me another one. I can't. I can't and it's unreasonable to ask me to in view of the fact that there's an incomplete data set here.

The burden of proof here is on these plaintiffs. It is not on the Harts to show that the company was perfect. It's not on the Harts to show even that it was compliant, not even to show that it was in material compliance although we think we have shown that. So this was, when I opened, I said to the Court we have two major questions here. One is was the company compliant in all material respects with applicable regulations. The question here, as the Court properly noted, is materiality. The second question is was Femtelle destined to fail. Not the Femtelle 2009 application, but was Femtelle destined to fail or, on the other hand, did plaintiffs fail or omit, omit to get it approved and marketed.

I'll talk about compliance first. The issue --

THE COURT: I must say I'm a little bit confused. I almost hate to ask this question. I'm a little bit confused about the incomplete data set argument. You're not talking about spoliation anymore because these records go back years and years and years before any of you were served, so I don't quite understand what you're saying. If there's no spoliation with respect to these types of records from back in '04 or '05 or '06, if they're not complete, one can still look at the

records that do exist and that's what Ms. Hagberg brought out in her redirect examination of Ms. Kuehn today.

MR. VELIE: Yes.

THE COURT: She said look, doesn't matter what else you find, you still have records that show, for example, that products were expired or that dates were extended, that crossouts were made changing numbers. That's still all wrong, it doesn't matter what else you find that was right, that's wrong and no document can change that. And so working with the records that do exist, of which she reviewed 100,000 records, that's a lot, she still found a fair amount of evidence of non-compliance.

MR. VELIE: I totally agree. But that evidence is totally out of context. We have no idea how many other records there were.

THE COURT: It doesn't matter.

MR. VELIE: But it does.

THE COURT: No, that's her point. She's saying in some instances, fine, you were able to show, she says there was no signature, there was a signature, that troubled her, troubled me. But in other instances such as extending expiration dates or changing batch numbers or drawing crossthroughs or whatever, there were a lot of things like that, doesn't matter what else you found, the ones that were reviewed showed non-compliance.

MR. VELIE: Thank you, your Honor. That's exactly the issue and let me address it this way. It's not a spoliation issue. It's a context issue. Let us suppose, let's take hypothetically that on day number one somebody down there in the research department, Ms. Gaikwad, crosses out something that she shouldn't have crossed out.

THE COURT: Okay.

MR. VELIE: What we don't know is whether on day two somebody said, look, that's a violation of the regs, let's do this the right way here's another document, sign this one. We just don't know. I can't disprove all of these things because we have no idea how many are missing. Therefore the ones that are there and are pointed to by Ms. Kuehn are almost certainly completely out of context.

THE COURT: I don't really follow that, I must say. We're talking about 100,000 records were reviewed. She found examples after examples in different categories of non-compliance. Not just one category, not just no signoffs, not just changed dates, not just crossouts, not just expired materials, but all kinds of problems. There are regulations governing this industry and what was of concern was that she found so many examples of non-compliance.

MR. VELIE: I understand. I understand your concern, your Honor, and I know exactly why she said that and what the plaintiffs pointed out and let me say if that was the only

proof in the record that would be impressive. But the rest of the proof in the record is we have no idea how many other documents Ms. Kuehn did not look at. Please, what I'm trying --

THE COURT: I don't know what evidence you have of that other than your say-so.

MR. VELIE: I asked her, do you have any idea what's missing. No.

THE COURT: You're starting with your developed view of something being missing. I don't know what proof there is of what's missing other than what I've already addressed in various opinions over the years, you know, if somebody deleted Mr. Hart's e-mail, fine, but we're not talking about Mr. Hart's e-mail here, we're talking about company records, design history records, not Mr. Hart's e-mails, or for that matter Ms. Ayres' e-mails. We're not talking about that kind of record which I've addressed for a different purpose. We're talking about company records. You presume hundreds of thousands are missing but I don't know what the proof of that is.

MR. VELIE: Judge, allow me to give an answer in context which will take perhaps 45 seconds to do. Number one, compliance, as we have seen repeatedly with everybody who talked about is not a matter of doing everything perfect.

THE COURT: No, I agree, and I've stated it for the

record. Perfection is not the standard. The standard is to have procedures in place, do the best you can and if you have problems you're supposed to try to correct. I understand that.

MR. VELIE: Bingo. That's step one. If you do something wrong, try to correct it. What Ms. Kuehn has -- what Ms. Kuehn has pointed out is a number of instances, I don't know whether it's 20 or 30 or 40, whatever it is, where they did something she says is wrong, okay?

THE COURT: Yes.

MR. VELIE: The next question is did they do anything compliant with respect to that wrong thing and therefore they utterly fail in their proof because the one thing we do know is the data set she was looking at was incomplete. Now, the point of my cross-examination is not, oh, you were wrong because this had a signature. It was Ms. Kuehn would you please consider whether or not you got all the documents. And this morning she acknowledged, I didn't have to show her anymore.

THE COURT: Of course not, because at the end of the day yesterday you were able to pull up four signature pages that she thought were unsigned and she was troubled by that.

MR. VELIE: Yes.

THE COURT: I still don't know what level, what quantity of material is allegedly missing. I don't know and you don't either. That's the problem.

MR. VELIE: Nobody knows and that's why --

THE COURT: I'm not sure it's missing at all because even the ones she didn't get when she said obviously she didn't get a complete data set, as Ms. Hagberg pointed out you did have those completed pages. They weren't missing at all, they just weren't given to her, those four pages. They were given to you, so they weren't missing. You got them. She should have gotten them. She didn't. You did. The company gave them to you. I don't know if anything is missing. I'm confused.

(Continued next page)

MR. VELIE: Nobody does, but the one thing --

THE COURT: No, you're arguing that lots is missing. I don't know if that's true. It's an argument, not evidence.

MR. VELIE: Let's take the facts that we've got and see if there are fair inferences that could be drawn from that. We know that she did not get a complete data set.

THE COURT: She didn't, but you did in that example. You got those four signed pages.

MR. VELIE: Judge, forgive me for saying this, but I really need to say two or three sentences in a row.

THE COURT: Yeah, but I need to keep making the point that raised the question that's concerning me. She may not have gotten it, but there wasn't missing --you got it.

MR. VELIE: I'm addressing that question.

THE COURT: All right.

MR. VELIE: By whatever windfall, we got some documents, maybe 30 or 40, that I was -- I will represent to the Court if you want, that I was prepared to show about 30 instances where I had some documents and she said absolutely they didn't exist. Now I know and you know and we all know that I don't have all the records of the company.

THE COURT: I don't know. I know you don't have the access, but I don't know that you didn't receive them. I don't know that there's anything missing. That's my problem. It's good lawyer --

MR. VELIE: Believe me, I'm getting there in a couple of sentences.

THE COURT: It's good lawyer argument, but I'm looking for the evidence.

MR. VELIE: I'm looking for inferences from the evidence that we have, because we do not have any certainty here. We have no certainty. The one thing we are certain of was she didn't get a complete data set and somehow or other I got some documents and was able to get her to agree with me that she didn't get all the documents. Okay.

But the one thing she readily agreed with, as a person who says she has experience in compliance, is she has no idea how much was missing. And she agreed with me in a context terribly important, and she agreed with me that she was less certain of her conclusions as a result of this. In other words, I think that the fair inference -- and this is not an inference from spoliation, I'm not claiming that these were destroyed willfully, I have no proof of that. I'm saying for whatever reason, they don't have a complete data set. Accordingly, it is impossible for her to say that they are noncompliant, meaning that they didn't address the issues that she saw.

THE COURT: Where we're parting company is your phrase, they don't have a complete data set. What is your proof on that?

MR. VELIE: Ms. Kuehn's testimony.

THE COURT: And I keep arguing with you. She may not have seen it all, but you may have been given it all. I don't know where the proof is that anything's missing. I know she didn't see it, but I don't know that it's missing from the company records that were produced to you.

MR. VELIE: Okay. I can make a representation about this, but it doesn't matter, Judge, I have no burden here.

THE COURT: No, you don't.

MR. VELIE: Okay. So I represent to you that we did the best we could to show what was missing. However --

THE COURT: Missing from her review.

MR. VELIE: Yes.

THE COURT: Okay.

MR. VELIE: That's all we're looking at here, what's missing from her review.

THE COURT: No, you're saying records are missing, and nobody will know ever how many are missing and how it would affect the analysis. I don't know if anything is missing. I know there were certain records she didn't get.

MR. VELIE: Okay, let's start with that.

THE COURT: Yeah.

MR. VELIE: The records she didn't get.

THE COURT: Right.

MR. VELIE: Therefore her testimony is less certain.

THE COURT: Right.

MR. VELIE: Than it should have been. Okay. And why is it less certain? Because there is no context.

THE COURT: But she was -- that was rehabilitated on redirect. Ms. Hagberg's redirect this morning took her through every category of noncompliance and said, even if you saw another batch that was compliant, that wouldn't change this noncompliant batch, for example. Even if you found other design histories, that wouldn't change the lack of design history, even if find some dates that some products that wasn't adulterated, that wouldn't affect the ones that used expired materials, and of course she agreed with all that over and over.

MR. VELIE: Of course.

THE COURT: She said yes, that's right, that's right, that's right, so.

MR. VELIE: Okay, but I recrossed and I got up and I said isn't the context important? And basically what I was asking and I believe I actually asked it, but forgive me if I get the transcript wrong, you've got a transcript, something that was wrong on day one could have been fixed on day two. That's the problem here. We don't know, she doesn't know. And she and Ms. Hagberg are the people who have to show you that it was noncompliant, which means not only was something wrong done, but that it wasn't properly addressed and that it was

material. We don't have that in this record.

THE COURT: Okay.

MR. VELIE: The other thing is we certainly know that she claimed that there were missing DHF's, design history files. We know that's false. How do we know that's false? I argued this just a few minutes ago.

THE COURT: Yeah.

MR. VELIE: You need them. You got to have them. They were there. They were rewriting them. So perhaps I'm doing this too much and forgive me if I am. But the plaintiffs who have the burden came to this Court to say from an incomplete data set, here are the problems, when in fact nobody from that incomplete data set could say that these --

THE COURT: The only problem is with the words incomplete data set. It's something that you said about 100 times. So if people repeat it enough, everybody starts to believe it, but I don't know that it's incomplete, okay. Can we move on? I think it's the argument is well --

MR. VELIE: I'm going to respond only to that.

THE COURT: Because the argument's well developed.

MR. VELIE: Thank you, your Honor. The only response I'm going to make to that is Ms. Kuehn could only testify to from what she saw which is --

THE COURT: 100,000 records.

MR. VELIE: And what she agreed was she knows that

that's incomplete and she has --

THE COURT: Because you have some paper that she doesn't have. That's why she knows it's incomplete.

MR. VELIE: I asked her, will you agree with me your set was incomplete.

THE COURT: Right. Of course she said yes because she knows you have paper that she doesn't. I don't know if it's 30 pages incomplete or 50,000 incomplete, I don't know it's incomplete at all. I know -- we're going in circles. I know she didn't see everything you had, okay.

MR. VELIE: No, I asked her the next question. Do you have any idea how many documents you didn't get.

THE COURT: Of course she doesn't.

MR. VELIE: Thank you, that's all my point.

THE COURT: The question is do you have any idea whether you didn't get every document, you know, in other words, I don't know there is any incomplete data set, but we've covered it so let's go on. Are we ready for --

MR. VELIE: Thank you for your patience.

THE COURT: Are we ready for Femtelle? Where are we up to.

MR. VELIE: No -- well, maybe we are.

THE COURT: Okay.

MR. VELIE: The issue as we set out in opening I think is fairly phrased as do you prefer the evidence of 13 audits or

inspection before, during and after the relevant period from '06 to '09, or Ms. Kuehn's opinion and some anecdotal proof, okay. Every single audit was passed. Now it's possible --

THE COURT: Well, no, you see that was opening then we had a trial --

MR. VELIE: Yes.

THE COURT: -- for five days.

MR. VELIE: I put in the 13 --

THE COURT: Hold on. What I've learned I think that audits or inspections aren't passed, they're opened and closed. Deficiencies are noted, deficiencies are sometimes corrected, life goes on. Certainly none of them were failed. I'll go that far. They were closed. They weren't failed, but it's not a good seal stamp of approval either. It makes observation. Those observation repeat, sometimes the same observation has appeared in more than one audit or more than one inspection. Problems were noted.

And also I don't know that inspectors or auditors can see 100,000 records over six months of studying and look at everything. They're there day or day and a half, they're doing on-site looking around, they're talking to people and they're examining some records. I don't know that their job is the same as hiring, you know, a private investigator to go to sit down and go through 100,000 records and come up with a full analysis.

MR. VELIE: May I respond?

THE COURT: They're not what -- these things maybe are not what you say they are.

MR. VELIE: Some of them are. All of the INTERTEK audits, which are substantial number of these --

THE COURT: They are, substantial.

MR. VELIE: End up with a certification. The company is certified as compliant. So it's not just we had some observation. They give a certification. That is a task, okay. And we saw --

THE COURT: Only answer to that is that's not the FDA, that's still not the FDA.

MR. VELIE: Understood.

THE COURT: That's a privately hired entity, may have its own relationship and interests in being rehired, it may have its own motivation. I can't judge the thoroughness of that particular audit. I don't know how it was conducted. There is no testimony, other than the document itself, reveals the conclusion. But I don't know what that auditor did, what that auditor reviewed. I don't -- just all I can read is the findings and then in the case of INTERTEK, final certification.

MR. VELIE: That's all correct, your Honor. However, the point is every year within the relevant period they were certified by an audit team.

THE COURT: From a private entity, certainly not the

FDA.

MR. VELIE: And twice within the period FDA mandated within the relevant period of time. It was FDA before and after, but during the relevant period, two FDA mandated audits by customers, okay. One was by Siemens and one was by Trinity Biotech. These were under the QSRs; in other words, these are for FDA compliance. And these customers are obligated by the FDA to make sure that everything is exactly the way it's supposed to be or they can't buy from ADI.

Now, we read to you extensive portions from the Trinity Biotech largely to prove to Mr. Fryer that his contentions about expired raw materials was utterly false, because the Trinity Biotech auditor made specific findings, that there are were good systems in place with respect to the company and the use of materials.

The second audit was by Siemens, and we know Siemens means business. They're not doing this as a slap-thing because in 2012, three years after we sold the company, they flunked Sekisui. These people know what they are doing, and they went in there and they looked and they flunked Sekisui, but they passed ADI. Now, it may be that it would be interesting -- oh, and nobody disputes, Ms. Kuehn told us, that the ISO regulations were there, and the FDA went and changed their regulations to bring them into compliance with ISO. So these are very close, and on a number of these audits, particularly

the customer audits, they do it the same time, ISO and QSR. No, really no difference.

THE COURT: ISO and FDA?

MR. VELIE: Yes.

THE COURT: You said QSR.

MR. VELIE: Yeah, QSR means FDA.

THE COURT: Oh.

MR. VELIE: QSR is quality system relations.

THE COURT: I know. That means FDA?

MR. VELIE: Yeah, that's what it means.

THE COURT: Okay.

MR. VELIE: What the FDA requires --

THE COURT: Yes.

MR. VELIE: -- is a QSR certified company, okay. So the INTERTEK auditor, Siemens or whoever it was, the ones who do both, Siemens and Trinity did both, QSR meaning FDA standards and ISO, passed. There wasn't even a finding of Trinity Biotech audit. They didn't find anything to complain about. In Siemens it passed, then later Siemens, who does mean business, flunked.

Now, you could argue, and they might argue, if they ever get a chance to argue it again, okay, well, they didn't catch me this time, you know, I was speeding, they didn't see, or you know, they only do a certain narrow set of questions. But 13 audits in every year, I mean there is one in or more in

every year. What are the odds that a company that would be as rotten as they complained it would be, would pass every single one of them?

The next point is, and this I think is a terribly important point. Ms. Kuehn said the observations in these various audits, they supported her opinion. But what does that really prove? What it proves is observations were made, the audit team didn't think they were sufficiently material not to grant a certification or to say, look, you're not QSR compliant. They said you're fine. Ms. Kuehn, on the other hand, says oh, no, this is terrible. What this really proves is that Ms. Kuehn, to Ms. Kuehn everything is terrible. We can't trust her judgment on what's material and what's not for a couple -- number of reasons. One is that. But the other is as you saw is, he has no experience. She's never even seen an audit. She never sat through an audit. She was never paid to help anybody.

THE COURT: No, she really is just somebody who reviewed the documents with an education.

MR. VELIE: Thank you, your Honor. That's exactly the case. So what is the issue that has to be addressed here? A company says we warrant that we are in material compliance with all applicable regulations, and they got a record shows they're audited 13 times. No problems. What more can you do? I mean say look I never had a document with a cross out on it? Nobody

could pass that standard. That doesn't exist. That's not materiality.

THE COURT: But using expired materials is troubling.

MR. VELIE: It could be troubling if we could, there were proof that --

THE COURT: There is proof of using expired materials. I saw it in the documents as I sat here for five days.

MR. VELIE: But we have --

THE COURT: There were batches and batches of expired materials. You don't remember seeing any expired materials?

MR. VELIE: There were expired materials, but where do they show there were actually used? It was like one or two anecdotal documents with a cross out. It turns out that that was a special order from somebody who specially tested it. That's all it was. That's the thing that Fryer looked at. That's the only record they've got. Is that the use of expired materials in a way that says we were materially not compliant? I don't think so. And I don't believe that you could so find. In addition --

THE COURT: I don't know without rereading this entire record whether there is only one or two pieces of exhibits that showed expired material being used in these kits. I thought there was more than one or two. That was my memory.

MR. VELIE: Maybe there were, maybe there were. But the real question is was the company compliant. Was the

company compliant means that have a system to deal with the problem of maybe using a raw material that shouldn't have been used. And the answer is, among other places, it's in several audits, but the one I happen to recall is Trinity Biotech, and I read it out, because they have procedures that Trinity Biotech went and looked at and said this is grand, this is perfect. They've got procedures to make sure that they don't use expired materials improperly.

THE COURT: Seems like the process didn't work then, because they used expired materials more than once, but okay.

MR. VELIE: Maybe they did, Judge. But I don't think that's material noncompliance. Because we just don't know from the records whether the next day somebody said you shouldn't have done that, don't do it again, here's a new label to use, we just don't know.

Okay. I think we may have exhausted the issue of Ms. Kuehn's conclusions.

There is one other thing I like to say about Ms. Kuehn and that is her method is retrospective. Your Honor already noted that.

THE COURT: Yeah, I mean it's really not about Ms. Kuehn, it's really about the documents she reviewed and what they revealed. And there is whole notebook of records that she says showed noncompliance.

MR. VELIE: I spoke about this earlier in the context

of the motion, but I'll just revisit very briefly. You tell me if you've heard enough, and that's the issue of the central narrative of the plaintiff's case, because it's completely bogus. That's Mr. Morrissey, the white knight coming in, when in fact the proof showed, as your Honor noted, he was possibly a bufoon, I don't know whether he was acting in good faith or bad faith or just idiocy, but whatever it was they fired him for his incompetence, and I find it troubling that --

THE COURT: Well, I do too. Morrissey is a troubling character in this drama.

MR. VELIE: Thank you, your Honor.

THE COURT: No question about that. So now are we ready for Femtelle?

MR. VELIE: Let me see if I need to say a word about Ms. Gaikwad or Hugh Fryer what he said. Oh, I do need to say something about this. This does have to do with spoliation. Both Ms. Gaikwad and Mr. Fryer, basically what they're saying is there's something wrong with the manufacturing process; they're not following the recipe, they're using expired material, whatever it is, and we made complaints to Mr. Hart and he didn't respond. Well, we proved that's not true. We saw complaint that Ms. Gaikwad made to Mr. Hart and he responded. He responded appropriately; hey, let's call a meeting, this is all wrong, we got to fix this. But where are the other complaints to Mr. Hart? We know where they are.

Hugh Fryer collected them. We have an e-mail chain from Koseki, it ends up with Dicey Taylor, the document destroyer saying Hugh Fryer's got all of these, he collected them, he's given them to me, and nobody seen them since. They didn't see them in their preparation, they didn't put them in a trial. They don't exist. We know that the e-mails of Leigh Ayres and Richard Hart were destroyed and they were willfully destroyed, and with them went all proof of what might have been said if somebody raised a problem about manufacturing. I believe that that's one of the places where your Honor ought to put the inference and say we're entitled to an inference that they responded to this, that they responded to it appropriately, and that the way a compliant company in management would.

Okay, now I'm ready for Femtelle, if you're ready for Femtelle.

The question here was Femtelle destined to fail. And as to this, there was no proof whatever by the plaintiffs. They put in proof that the 2009 Femtelle application was destined to fail, but that doesn't mean that Femtelle was destined to fail. In fact we know why the, we know the exact --

THE COURT: But their argument is for the reasons that the 2009 Femtelle was destined to fail, any application was destined to fail. There's no clinical data, there is no design history files, it can't be made up now. The problem can not be

corrected, it's over. They made a business judgment, it would have taken millions of dollars to reconstruct records that were gone. You may call them 20 year old records. You can call them anything you wan, but they're gone. And they can't put in an application without it. In fact, you just said although products that this company sells must have had design history files or they wouldn't have gotten 510(k) approval. There is one thing that seems clear is that the clinical data of the trials here is gone with respect to Femtelle. I don't know why it's gone, but it's gone.

MR. VELIE: Okay.

THE COURT: But they would have put it in, you would have put -- somebody -- the prior company, Sekisui. It doesn't exist, it's gone.

MR. VELIE: Okay. We got to remember what design history means. Design history means either the notebook that you had or information that is referred to, can be referred to, okay. That's what it means.

THE COURT: And that information could be clinical trials and the results of those trials.

MR. VELIE: It could be.

THE COURT: And it's gone.

MR. VELIE: No, it's not gone. You have to remember what the FDA --

THE COURT: What do you mean, no it's not gone, where

is --

MR. VELIE: It's not gone.

THE COURT: Where is your evidence?

MR. VELIE: I'm about to tell you the evidence. The FDA sends an e-mail on June 28.

THE COURT: I remember it says give us what you have.

MR. VELIE: It says, get the information from your investigator, and then for your records, meanwhile give us everything else that we've asked for.

THE COURT: Right.

MR. VELIE: Okay. So it's not gone. The FDA apparently said --

THE COURT: It is gone. It says FDA says even if it's gone, give us what you have, we'll do the best we can, you should do the best you can, we'll look at it. Sekisui does not follow-up with that maybe because they know how little there is to give.

MR. VELIE: What's the it? The it is information.

THE COURT: Right.

MR. VELIE: Okay. The information is available with the investigators in Germany. It's there. She says go and get it for your records.

THE COURT: You can't.

MR. VELIE: No, they can. They never said they couldn't get it. They said they couldn't get it in time. I

think the record is very clear on this.

Anyhow, it was for their records not to show the FDA. For all we can tell, the FDA did not care. They said over and over again, FDA won't tell us whether not having some batch records from 20 years ago matters or doesn't matter. This was something that was never even asked for by the FDA. They volunteered it to the FDA. And then they kept asking is this a problem, is that a problem, is that problem? They were never told it was a problem. And then the FDA, the final thing the FDA says is get the information for you records. That's fine, it's available some place else. You told us that your investigator could get it, go get it. That's the it. It's available.

I think, though, that the real -- I think that the real response to this is the party admission, which is absolutely devastating to the plaintiff's contention here.

THE COURT: Oh, the 80 percent.

MR. VELIE: 80 percent likelihood of approval and marketability, 80 percent. So to come in here now and to say oh, well, you know, I'm looking at an old e-mail and they told him we can't find the batch records -- oh, it's all over. It's not all over. They knew it was an 80 percent chance and they omitted -- and that's the important thing, we didn't fail in our proof -- they failed in their proof. They didn't show us, as they were obligated to, that they had done something other

than just withdraw this thing voluntarily, apparently because they feared audit. They feared because Morrissey told you there is going to be an audit. I know it because I'm a great FDA expert. That's why they withdrew it. And the record is very plain that that's the case.

But the record is also clear that they had an 80 percent chance of doing it and they omitted to doing anything to do it. They didn't even try again, even though Mr. Fryer testified he recommended that they do it. He also put in his report to the management, the questions they asked us in the may comments, which were the comments everybody's going back and forth with to the FDA in 2009, 2010. That's May of 2010, right before they withdrew it. He says, those are softball questions, we could have answered those, but we withdrew it. That's a party admission. If your Honor needs it, I'll get you the exhibit for that. It was used during Fryer's cross-examination. Your Honor, I'm without reference to it, but surely you remember Mr. Fryer writes a report and he says I recommend we do an IDE, and he explains what the IDE is; in other words, he's recommending that they go forward with Femtelle. And there is a paragraph I called to his attention and read into the record -- I've got it. DX6K's and I'll read it into the record again. 4.42 on page 429 of 6Ks' August 29th, 2011. I'm on page 429 at Section 4.42. Many minor points were raised in these comments, meaning the FDA's

comments, all of which could have been answered by ADI. However, no actions were taken as the submission was withdrawn. That's Mr. Fryer, who, as your Honor noted, was an impressive witness. And that's Mr. Fryer when he was writing down the truth for his management and not coming here to testify for his company. I think it's plain from this that Sekisui did nothing to try to market Femtelle and to get it cleared, despite the recommendation of Mr. Fryer, despite Mr. Fryer's saying that they could have done it. It was easy, despite the FDA saying just get the information from the investigator for your records. They did nothing, and they were obligated by contract to do something, they were obligated by contract to do something. And it's not to use reasonably --

THE COURT: Oh, that's right. What about that argument they say you never proved the commercially reasonable standard?

MR. VELIE: There are two things they have to do. One is to use reasonable efforts, which is commercially reasonable standard, and the other is not to omit to do something to get it approved. This is a very broad, very important concession they gave to us. I'm reading from page 19 of the SPA, which I believe is plaintiff's Exhibit 3, 2.6(d)(1)(b). They promise, quote, not willfully to take any actions or omit to take any actions with the intent of preventing the business from meeting the Femtelle revenue targets set forth on exhibit A or from

satisfying the condition set forth in Section 2.6B or that could be reasonably expected to impair the ability of the company and its subsidiaries to maximize Femtelle revenue. They were obligated to do something.

THE COURT: Where is that phrase about commercially reasonable?

MR. VELIE: That's in the predecessor paragraph, which talks about, undertake commercially reasonable efforts --

THE COURT: Right.

MR. VELIE: -- to market and sell. So they've got two obligations. One is to do the reasonable thing that they're complaining we didn't prove, and the other is not to omit to do anything. And that's the one that we rely on and which is proved here.

THE COURT: So you're relying on which paragraph, 2.6?

MR. VELIE: 6 --

MS. BRILEY: 2.6(d)(1)(b).

MR. VELIE: You'll find it on page 19 near the top.

THE COURT: I got that. But did (d)(1)(b) as opposed to (d)(1)(a). You're saying (d)(1)(a) is separate obligation.

MR. VELIE: That's correct, that is the separate obligation. (d)(1)(a) is the one they're talking about, (d)(1)(b) is the one we proved.

THE COURT: So you're saying if they failed (d)(1)(b), that's enough to prove your case. You don't need to prove

(d)(1)(a).

MR. VELIE: That's exactly correct, your Honor.

Just a word about counterclaim damages. It's exactly as I put it when I opened. We proved that what the Harts gave up was their rights to Femtelle, and what they got back was a promise of an earn out. So their out of pockets, if you will, which is a proper contract measure of damages. You could even give benefit of the bargain or out of pockets.

THE COURT: I'm sorry what did you say, the out of pockets?

MR. VELIE: The out of pockets, what it cost them to get the earn out was to give up Femtelle. They gave it up. They don't own it any more.

THE COURT: Yes.

MR. VELIE: Sekisui owns it. So they gave it, they didn't get the earn out. That's a failure of consideration, breach of contract.

THE COURT: Yeah. And what's the damages?

MR. VELIE: So the point of this is to value the damages for what they gave up.

THE COURT: Yes.

MR. VELIE: Let's just look in their own document, their own accounting record of what they value Femtelle has, 2012, which is the relevant period, $3.6 million. That's what they took from the Harts and they failed to pay for it.

THE COURT: Where is the $3.6 million?

MR. VELIE: I'll show you, your Honor.

This is in defendant's Exhibit 4Js. You'll find it at page five, which is also 5023 of the Sekisui stamping system and it says -- this is KPMG writes to the company and asks the company questions. Please provide the carrying amount of Femtelle as of the valuation date. The valuation date I believe is October 1, 2012 as it says in the cover of this. So on October 1, 2012 Sekisui is carrying the value of Femtelle, which they did not pay for, at $3.6 million. At the very least, that's what they owe the Harts.

If your Honor chooses instead the benefit of bargain theory, then it's the value of the earn outs. I acknowledge, your Honor, that's -- there is less certainty in the earn outs because we'd have to predict what there is. I would actually argue that they're estopped not to use the projections, but I don't think we need to get into that. We'd be satisfied if we got back what we gave them, that's $3.6 million.

THE COURT: Can we go back to their argument that Femtelle had a value of the 25.5 million purchase price?

MR. VELIE: Yes. Would you like, what would you like me to do about that?

THE COURT: Well, tell me your view. They say --

MR. VELIE: Oh, it's --

THE COURT: -- in their chart of Erb that it's 12 and

a half million dollars because KPMG said so in its valuation in October as of the closing date in April or March. That's what it was.

MR. VELIE: Okay.

THE COURT: And then Erb also points out that had to have a value because the earn out doesn't pick up until the first two and a half million is sold in 2010, and then four and a half million in 2011, et cetera. So theoretically, Sekisui was going to get $20 million of revenue before paying any earn outs, so it must have had a value in the purchase price and some evidence that they wouldn't have even been interested in buying this company but for Femtelle.

MR. VELIE: Let's --

THE COURT: Did it have a value, any part of the 25.5 million if so how much?

MR. VELIE: None, and that's clear from the evidence. What Mr. Erb is looking at is things that happened after the acquisition. What he's --

THE COURT: He has to know. I made that argument with him too about the KPMG in October, but KPMG says we're doing it as of the closing in April. We're looking at the documentation then, we're looking back to the confidential memorandum. It did have a value and look at Exhibit A to the SPA. It clearly had a value because they weren't paying a earn out until $20 million was earned by the company from 2010 from to 2013 and

evidence they wouldn't have been interested in buying it but for Femtelle.

MR. VELIE: Okay, allow me to deal with this. The first thing is what about the valuation. I believe you asked Mr. Erb or possibly Mr. Kortmansky asked Mr. Erb, this was done after the acquisition. Nobody's contending that it was used by them.

THE COURT: Right. I did all that. I didn't rely on, it didn't exist until October.

MR. VELIE: So that's the first thing.

The second thing is let's look what they actually did, and we did quite a bit of that. We looked at what their investment bankers told them. Their investment bankers told them don't pay a penny for it, use the earn out method, it's too uncertain, okay, that's what's investment bankers advised. And here --

THE COURT: They didn't present it to the board.

MR. VELIE: Well, wait a minute. That's if you believe them. What's the credibility of this? This is a Japanese manager, Mr. Takemura -- I assume he's still with us.

THE COURT: I don't know.

MR. VELIE: Who says look I went to the board three days after I got this thing, but I didn't tell them that the --

THE COURT: What --

MR. VELIE: I was told not to pay a penny for it,

okay. Do we believe that from somebody who tells us, oh, my God I got scolded? What man -- he. Nice of Mr. Erb to say this, but real world, what manager would not cover his back side and say I've got an investment banker, this is what the investment banker -- I don't think we can credit Mr. Takemura when he says that.

THE COURT: Okay, but what about KPMG?

MR. VELIE: Okay, let me leave KPMG for last.

The next thing we have is Mr. Takemura actually does some calculations. I took him through it. Remember the little red box.

THE COURT: I do.

MR. VELIE: This is what we value the company, the following three things are how we valued he company. And we look up and there are three bars. And with respect to each of the bars, the value of the company without Femtelle and decided 25.5 million. Then Mr. Takemura says, well, yeah, but we wanted Femtelle. Sure he did. Of course he did. It could have been valuable. So how did they get Femtelle? They offer an earn out for it. They didn't pay a penny for it.

THE COURT: You're ignoring exhibit A which Mr. Erb did a good job of. He points out that exhibit A doesn't kick in from dollar one. The company gets a total of something like 20 million over four years of revenue 2010 to 2013 without any earn out.

MR. VELIE: Very interesting, but it's not relevant, because that just shows that the company got a really sweet deal. They don't even have to begin an earn out paying until they --

THE COURT: He says because we paid for it up front, we paid something for Femtelle.

MR. VELIE: How does he know what they paid for it? What we know is that they didn't pay for it. $25.5 million was analyzed, and said this is the value of the company without Femtelle, if we'd like to have Femtelle, let's do essentially what the Savvian told us to do, we'll give them an earn out, but --

THE COURT: Then why weren't they getting a penny on every dollar? Why wasn't -- if you talk about an earn out, hold on -- talk about earn out, why isn't the Harts getting a penny on every dollar sold?

MR. VELIE: Because Sekisui drove a hell of a good bargain. The Sekisui bargain is this, we'll give you an earn out, but first we have to rake in a lot of bucks.

THE COURT: Right.

MR. VELIE: That doesn't mean they paid for it. It means they got a sweet deal. They don't have to pay until all those millions are in, then they have to pay.

THE COURT: Maybe they paid.

MR. VELIE: Maybe they paid. There is no proof that

they paid. What we have is the speculation from a valuation done by KPMG for totally different purpose. In fact there is an excellent reason to give Femtelle a huge mark up in that thing. Why? It's a chancy product. If it fails, huge tax write off. That's in fact what they did. There is no credibility in the suggestion that the company had in mind that Femtelle is worth $12 million and we're going to pay that in cash in order to get Femtelle. They were told not to do that, they never wrote a memo to the board saying hey this is what we're doing even though we're told not to do that.

THE COURT: No, I never said 12 million, but --

MR. VELIE: That's what they're saying.

THE COURT: I know it's what he said. I haven't brought into the 12 million yet, but it had some value, part, some part of that purchase price is what I'm asking you.

MR. VELIE: Of course it has a value. Let's put it this way. Is it fair to get a purchase price adjustment of let's say $12 million when you don't pay any cash for the thing that you got and you have no obligation to pay an earn out, is that right? Well, that's what Mr. Erb has done with his jiggery pokery. This is just magic. He says, okay, I'm going to take this completely different analysis after the fact.

THE COURT: Well --

MR. VELIE: I'm going to say woo --

THE COURT: That number comes from somewhere. It came

from the company.

MR. VELIE: Confidential memorandum.

THE COURT: Yeah, it did.

MR. VELIE: Okay. But they're not supposed to rely on that. And yet here they are in this courtroom, when they know they're not supposed to rely on it saying, oh, we relied on it, and we relied on it for purposes of getting a purchase price adjustment; in other words, this is what we relied on at the time. That, that just doesn't wash.

Do you have any other questions about damages?

THE COURT: No.

MR. VELIE: Okay.

I believe, I believe I have exhausted our topics.

THE COURT: I think that's right.

MR. VELIE: So in summation, which only takes a second --

THE COURT: Yes, it does.

MR. VELIE: -- we've got a claim which I think is not proved in view of all of these audits. And the fact that they are unable to say with reasonable certainty what it means if documents are missing, or to claim that documents means something when we don't have the context of those documents, in the face of 13 audits by independent people, audit teams who actually look at things, find problems that say these aren't material and many of them are the very same problems Ms. Kuehn

found, as she acknowledged. They're not material. Ms. Kuehn thinks everything is material. Okay. That's the claim.

What about the counterclaim? It is undisputed that 80 percent -- I'm not even going to fight about 2009. Following 2009, had 80 percent chance of success. They did nothing, and they're obligated to do something. And at the very least, we're entitled to $3.6 million.

THE COURT: Okay.

MR. VELIE: Thank you, your Honor.

THE COURT: Well, thank you all for your efforts this week on getting through this in five days. It's obviously a ton of evidence here and I know you all cut back and I know each side feels it could have put in more evidence, but there's already more one person can really fully digest and so you had to do it this way. I appreciate it and I look forward to your final annotated missions and supplemental submissions, and I'll get you a decision as soon as I can. Thank you.

MS. HAGBERG: Thank you, your Honor.

MR. VELIE: Thank for your patience, your Honor.

THE COURT: You're all excused. I have one more case today. Have a good weekend.

MS. HAGBERG: You too.

(Adjourned)

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